ASHLAND

Ashland Inc.

Thomas P. Baker
EHS Manager

Ashland Research Center
500 Hercules Road
Wilmington, DE 19808-1599
Tel: 302-995-3455, Fax: 302 995-3359
tpbaker@ashland.com

FEDERAL EXPRESS AND EMAIL

May 17, 2016

State of Delaware – DNREC
Division of Air and Waste Management
State Street Commons
100 W. Water Street, Suite 6A
Dover, DE 19904
Attn: Program Administrator

RE: Submission of Updated Air Quality Permit Applications for the Installation of Four Units that are part of the R & D Spray Drying Process at the Hercules Incorporated Research Center (a.k.a., Ashland Inc.), Wilmington Research Center, 500 Hercules Road, Wilmington, Delaware, Current Permit No. AQM-003/00017(Renewal 1); an Air Contaminant Registration Application; and updated site Potential to Emit Calculations

Dear Sir or Madam:

We want to thank the DNREC Air Permit team for meeting with us on May 2, 2016 at the New Castle office to discuss our permit status for the referenced facility. As requested at the meeting, Ashland, Inc. is submitting the following documents to correct and clarify emission information and potential to emit calculations:

1. Updated permit applications for the installation of four dryers that are part of the process to be used for R & D purposes for the pharmaceutical industry and will consist of the following equipment:
   - One R&D Spray Dryer (closed loop system with internal condenser integral to the process);
   - One GMP Spray Dryer (closed loop system with internal condenser integral to the process);
   - One SD Micro Spray Dryer; and
   - One MP-1 Fluid Bed Dryer

   The emissions from the four listed units will be controlled by two, 2000 lb. carbon adsorbers in series. We request that each permit reflect the maximum pound per hour emission rate for each individual solvent used at one hundred percent and a total VOC and HAP ton per year emission level based on the typical solvent mixture as provided in the application information.

2. An updated AQM-4.2 to request a change from our previously requested carbon bed leak check process, the details of which are included in Section 27.1.

3. An Air Contaminant Registration Form and supporting documents for a small dryer (Buchi) in building 8162A.

4. An updated site potential to emit spreadsheet incorporating all emission units for the site. All spreadsheets included with the submittal will be included with the electronic submittal.

If you have any questions regarding the information provided herein, please do not hesitate to contact me at 302-995-3455 or via electronic email at tpbaker@ashland.com.

Sincerely,

Thomas P. Baker

Ashland, Inc.

Enclosure

Administrative Information

DNREC – Division of Air Quality
Application to Construct, Operate, or Modify Stationary Sources

Administrative Information

One original and one copy of All Application Forms Should Be Mailed To:
Air Quality Management
100 West Water Street, Suite 6A
Dover, DE 19904

All Checks Should Be Made Payable To:
State of Delaware

Company and Site Information

1.	Company Name: **Hercules Inc.**		
2.	Company Mailing Address: **500 Hercules Road**		
	City: **Wilmington**	State: **DE**	Zip Code: **19808**
3.	Site Name: **Ashland Inc. Wilmington Research Center**		
4.	Site Mailing Address: *(if different from above)*		
	City:	State:	Zip Code:
5.	Physical Location of Site: *(if different from above)*		
	City:	State:	Zip Code:
6.	Site Billing Address: *(if different from above)*		
	City:	State:	Zip Code:
7.	Air Quality Management Facility ID Number: **1000300017**		
8.	Site NAICS Code): **541712** *(list all that apply*		
9.	Site SIC Code: **8731** *(list all that apply)*		
10.	Site Location Coordinates:	Latitude: 39.758889 ° ' "	
		Longitude: -75.634722 ° ' "	
11.	Is the Facility New or Existing?	☐ NEW ☒ EXISTING	
If the Facility is an Existing Facility, Complete the Rest of Question 11. If Not, Proceed to Question 12.			
11.1.	Does the Facility Have Active Air Permits?	☒ YES ☐ NO	
12.	Is this Application For New Equipment or a Modification to Existing Equipment? ☐ New Equipment ☐ Modification of Existing Equipment ☒ Other (Specify): **Obtain air permits for three spray dryers and one fluid bed dryer that are all part of the R&D Spray Dryer Process**		
If the application is for the modification of existing equipment, complete the rest of Question 12. If not,			

Company and Site Information

proceed to Question 13.

12.1. Does the Equipment Have an Active Air Permit? ☐ YES ☒ NO

If the equipment has an active air permit, complete the rest of Question 12. If not, proceed to Question 13.

12.2. Permit Number of Existing Equipment: **At this time the site is operating under Permit AQM-003/00017 (Renewal-1) and is in the process of reclassifying as a Natural Minor Source**

13. Status of Equipment Being Applied For:
☒ Natural Minor Source
☐ Synthetic Minor Source
☐ Major Source
☐ Federally Enforceable Restrictions

14. Facility Status: ☐ Natural Minor Facility ☐ Synthetic Minor Facility ☒ Major Facility

If the facility is a Major Source, complete the rest of Question 14. If not, proceed to Question 15.

14.1. Responsible Official Name: **Michael W. Hassman**

14.2. Responsible Official Title: **Director, Facility Services**

Contact Information

15. Name of Owner or Facility Manager: **Michael W. Hassman**

16. Title of Owner or Facility Manager: **Director, Facility Services**

17. Permit Contact Name: **Thomas P. Baker**

18. Permit Contact Title: **EH&S Manager**

19. Permit Contact Telephone Number: **302-995-3455**

20. Permit Contact Fax Number: **302-995-3359**

21. Permit Contact E-Mail Address: **tpbaker@ashland.com**

22. Billing Contact Name: **Thomas P. Baker**

23. Billing Contact Title: **EH&S Manager**

24. Billing Contact Telephone Number: **302-995-3455**

25. Billing Contact Fax Number: **302-995-3359**

26. Billing Contact E-Mail Address: **tpbaker@ashland.com**

Proposed Construction and Operating Schedule

27. When Will the Proposed Construction/Installation/Modification Occur: 09/01/2015

28. Proposed Operating Schedule: **10** hours/day **3.5** days/week **52** weeks/year

28.1. Is There Any Additional Information Regarding the Operating Schedule? ☐ YES ☒ NO

Proposed Construction and Operating Schedule

If YES, complete the rest of Question 28. If NO, proceed to Question 29.

28.2. Describe the Additional Information:

Coastal Zone Information

29. Is the Facility Located in the Coastal Zone? ☐ YES ☒ NO

If the facility is located in the Coastal Zone complete the rest of Question 29. If not, proceed to Question 30.

29.1. Is a Coastal Zone Permit Required for Construction or Operation of the Source Being Applied for? ☐ YES ☐ NO

Attach a copy of the Coastal Zone Determination if it has not been previously submitted

If a Coastal Zone Permit is required complete the rest of Question 29. If not, proceed to Question 30.

29.2. Has a Coastal Zone Permit Been Issued? ☐ YES ☐ NO

Attach a copy of the Coastal Zone Permit if it has not been previously submitted

Local Zoning Information

30. Parcel Zoning: **Local zoning approval previously submitted**

Attach Proof of Local Zoning if it has not been previously submitted

Application Information

31. Is the Appropriate Application Fee Attached? ☐ YES ☒ NO

32. Is the Advertising Fee Attached? ☐ YES ☒ NO

For help determining your application and advertising fees see:
http://www.dnrec.state.de.us/DNREC2000/Library/Fees/DE%20Permit%20Fees.htm

Attach the appropriate fees. Note that your Application will not be considered complete if the appropriate fees are not included.

33. Is a Cover Letter Describing the Process Attached? ☒ YES ☐ NO

Attach a brief cover letter describing your Application.

If the Facility is a New Facility complete Question 34. If not, proceed to Question35.

34. Is a Copy of the Applicant Background Information Questionnaire on Record at the Department? ☒ YES ☐ NO

If NO, complete the rest of Question 34. If YES, process to Question 35.

34.1 Is a Copy of the Applicant Background Information Questionnaire Attached? ☐ YES ☐ NO

For a copy of the Applicant Background Information Questionnaire see
http://www.dnrec.delaware.gov/services/Documents/Chapter79Form.pdf

Attach a copy of the Applicant Background Information Questionnaire if applicable.

35. Check Which Application Forms are Attached:

Application Information

☒ AQM-1	☐ AQM-3.4	☐ AQM-3.9	☐ AQM-3.14	☐ AQM-4.4	☐ AQM-4.9	☐ AQM-6
☒ AQM-2	☐ AQM-3.5	☐ AQM-3.10	☐ AQM-3.15	☐ AQM-4.5	☐ AQM-4.10	
☒ AQM-3.1	☐ AQM-3.6	☐ AQM-3.11	☐ AQM-4.1	☐ AQM-4.6	☐ AQM-4.11	
☐ AQM-3.2	☐ AQM-3.7	☐ AQM-3.12	☒ AQM-4.2	☐ AQM-4.7	☐ AQM-4.12	
☐ AQM-3.3	☐ AQM-3.8	☐ AQM-3.13	☐ AQM-4.3	☐ AQM-4.8	☒ AQM-5	

36. Check Which Documents are Attached:

☐ Coastal Zone Determination
☐ Coastal Zone Permit
☐ Proof of Local Zoning
☐ Application Fee
☐ Advertising Fee
☐ Applicant Background Information Questionnaire
☐ Claim of Confidentiality
☒ Manufacturer Specification(s)
☐ Material Safety Data Sheets (MSDSs)
☒ Supporting Calculations
☒ Descriptive Cover Letter
☒ Other (Specify): **Application and Advertising Fees were submitted with the original application**

Confidentiality Information

37. Do You Consider Any of the Information Submitted With this Application Confidential? ☐ YES ☒ NO

For help on how to submit a confidentiality claim see
http://regulations.delaware.gov/register/december2011/final/15%20DE%20Reg%20864%2012-01-11.htm

If a Claim of Confidentiality is made it MUST meet the requirements of Section 6 of DNREC's Freedom of Information ("FOIA") Regulation at the time the Application is submitted.

Signature Block

I, the undersigned, hereby certify under penalty of law that I have personally examined and am familiar with the information submitted in this document and all of its attachments as to the truth, accuracy, and completeness of this information. I certify based on information and belief formed after reasonable inquiry, the statements and information in this document are true, accurate, and complete. By signing this form, I certify that I have not changed, altered, or deleted any portions of this application. I acknowledge that I cannot commence construction, alteration, modification or initiate operation until I receive written approval (i.e. permit, registration, or exemption letter) from the Department. I acknowledge that I may be required to perform testing of the equipment to receive construction or operation approval, and that if I do not receive approval to construct or operate that I may appeal the decision.

Michael W. Hassman
Owner or Operator

5/17/2016
Date

Signature of Owner or Operator

One Original and One Copy of All Application Forms Should Be Mailed To:
Division of Air Quality
Blue Hen Corporate Center
655 S. Bay Road, Suite 5 N
Dover, Delaware 19901

All Checks Should Be Made Payable To:
State of Delaware

Process Flow Diagrams

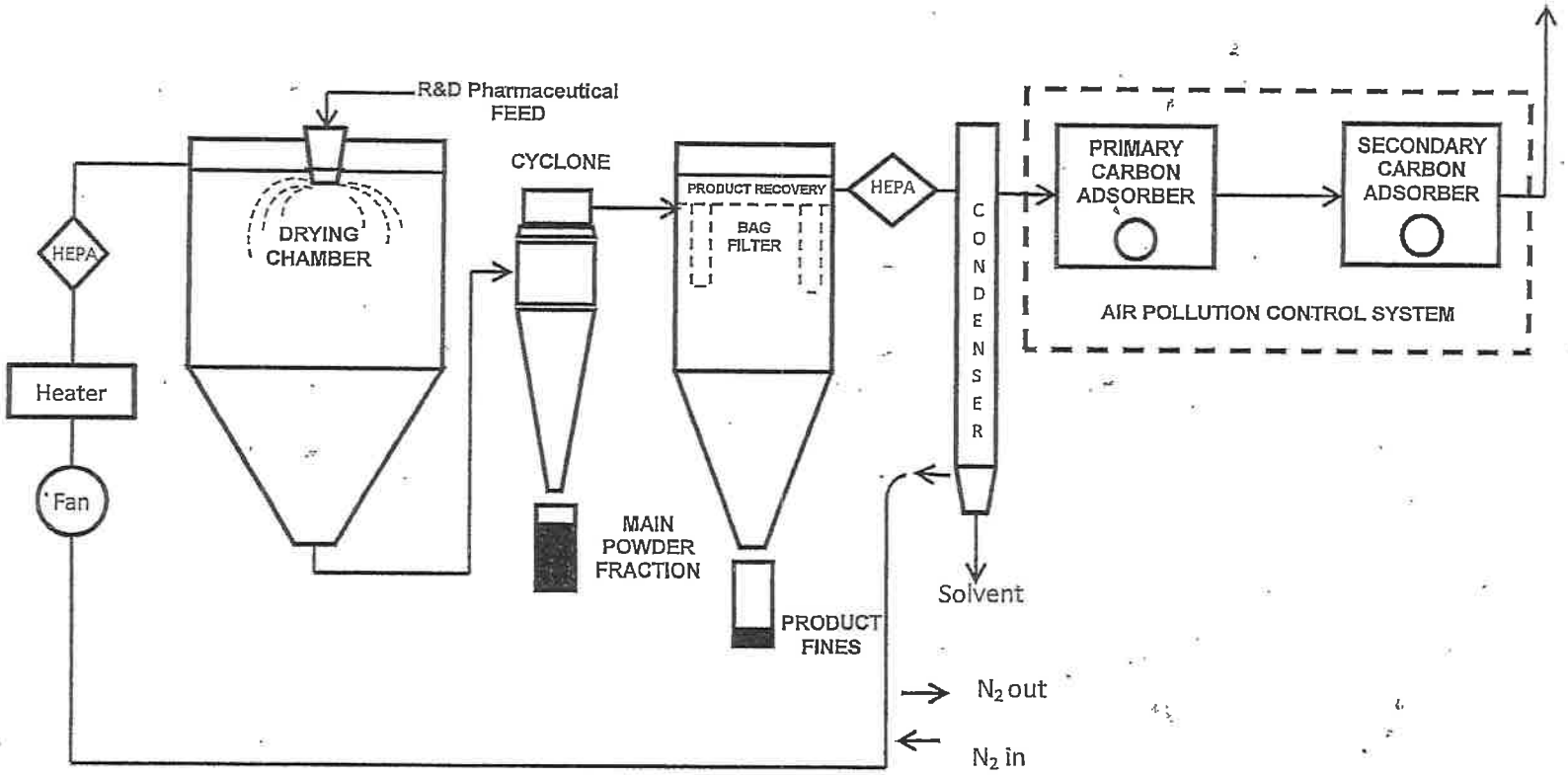
DNREC – Air Quality Management Section
Application to Construct, Operate, or Modify Stationary Sources

Process Flow Diagram

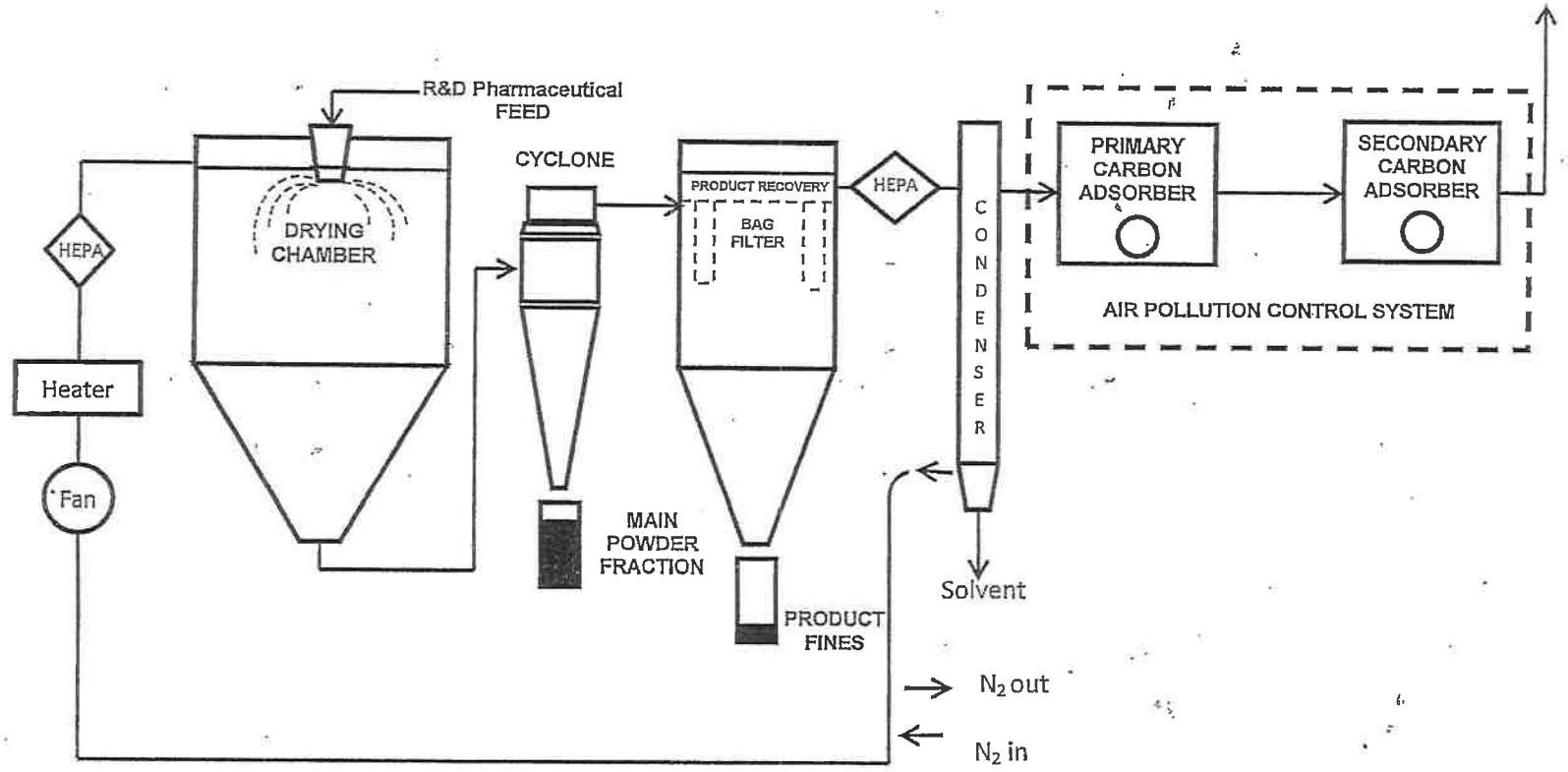
Sketch the Process Flow Diagram for the equipment or process being applied for. Include each emission unit and control device (even existing emission units that will not be modified by this application). You may identify each emission unit with a simple shape. Label each emission unit and control device with a unique identifier. Show the relationship between each emission unit and/or control device by drawing arrows between them to indicate the flow of air pollutants. List which application forms are included for each emission unit or control device below the shape representing each emission unit or control device . See http://www.delaware.gov/reg2/default.htm for example Process Flow Diagrams for common processes. If you already have a Process Flow Diagram for the equipment or process being applied for, you may attach it to the application instead of using this form.

See attached documents

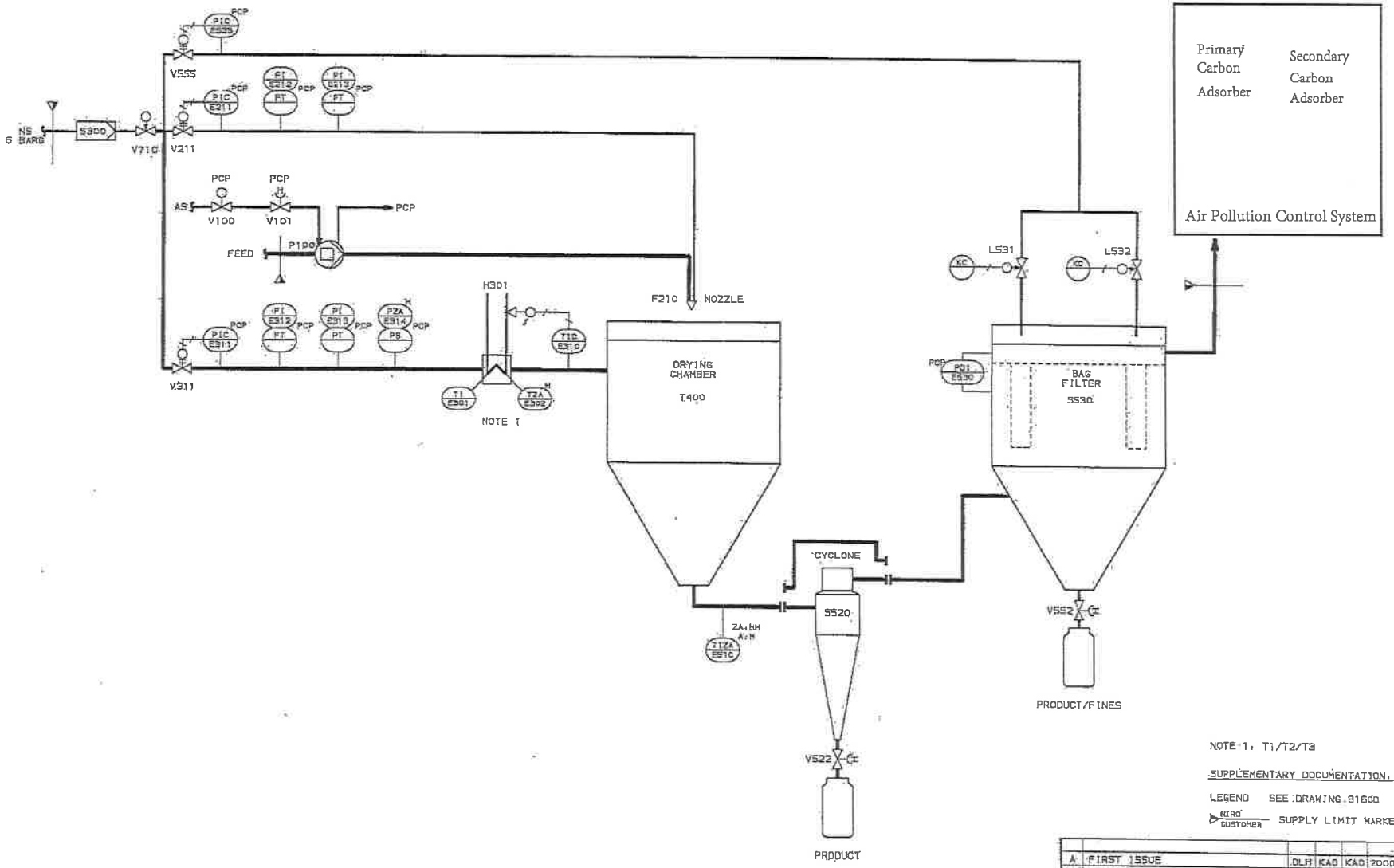
Process Flow Diagram for Co-Current Atomizer Spray Dryers:



Process Flow Diagram for Co-Current Atomizer Spray Dryers:



SD Micro



Rev	Description	Drwn	Check	Appr	Date
A	FIRST ISSUE	DLH	KAD	KAD	2000-11-28

GEA Niro A/S

SCHICRO INSTRUMENTATION FLOW SHEET-

ORDER NO.: 090-0007-00

Scale: -
Format: A1
Category: 3

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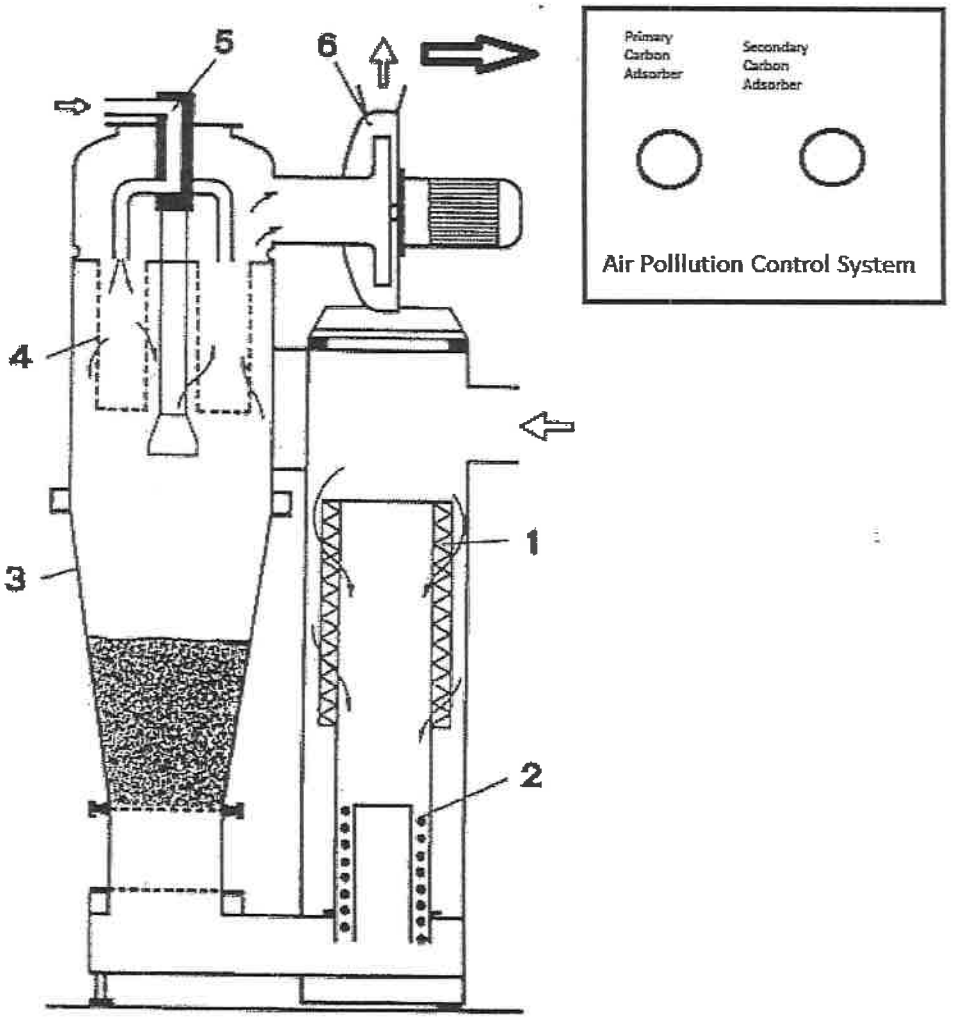
Document No. 248080

Rev A

MP-1



The principle of the fluid bed dryer consists in bringing flowable moist material like granules or powders to a liquid-like fluidized state by means of an upward heated air stream thus achieving a rapid and careful drying to the desired residual humidity.

The air necessary for this working process is sucked in by a fan (6) from outside, cleaned in the filter housing (1) and heated to the desired temperature in the air heater (2). The prepared air then flows upwards through the material in the product container (3) and absorbs the moisture of the product in the shortest possible time. Dust particles, carried along by the air stream, are held back in the exhaust air filter (4) and continuosusly reconveyed into the fluid bed zone by the filter blow-back device (5).

R&D

PSD-1

Spray Dryer

Generic Process Equipment Application

If you are using this form electronically, press F1 at any time for help

General Information

1.	Facility Name: **Hercules / Ashland Research Center**
2.	Equipment ID Number: **R&D PSD-1 Spray Dryer**
3.	Provide a brief description of Equipment or Process: **Small co-current atomized nozzle spray dryer for pharmaceutical research. The spray drying system includes a feed pump to pump the feed solution to the atomizer, an inlet gas heater to heat the process gas, a drying chamber to allow for the atomized droplets to contact the hot gas and dry the droplets, a cyclone, a baghouse and a HEPA to collect the product. The solvent evaporated in the drying chamber is recovered in a condenser for reuse/disposal. The uncontolled emissions are vented through two carbon adsorber beds in series.**
4.	Manufacturer: **Niro/GEA**
5.	Model:
6.	Serial Number: **093-1993-00**

Raw Material Information

7. Raw Materials Used in Process

If there are more than four Raw Materials used, attach additional copies of this page as needed.

	Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1.	**Active pharmaceuticals and excipients**	**N/A**	**Varies**	☐ YES ☒ NO
7.2.	**Ethanol**	**64-17-5**	**1986 kg/yr average**	☐ YES ☒ NO
7.3.	**Methanol**	**67-56-1**	**4088 kg/yr average**	☐ YES ☒ NO
7.4.	**Acetone**	**67-64-1**	**4088 kg/yr average**	☐ YES ☒ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Raw Material used.

Products Produced Information

8. Products Produced

If there are more than four Products Produced, attach additional copies of this page as needed.

	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.	**R&D pharmaceuticals**	**N/A**	**Various**	☐ YES ☒ NO
8.2.				☐ YES ☐ NO

Generic Process Equipment Application

If you are using this form electronically, press F1 at any time for help

General Information

1.	Facility Name: **Hercules / Ashland Research Center**
2.	Equipment ID Number: **R&D PSD-1 Spray Dryer – Additional Raw Material information**
3.	Provide a brief description of Equipment or Process: **Small co-current atomized nozzle spray dryer for pharmaceutical research. The spray drying system includes a feed pump to pump the feed solution to the atomizer, an inlet gas heater to heat the process gas, a drying chamber to allow for the atomized droplets to contact the hot gas and dry the droplets, a cyclone, a baghouse and a HEPA to collect the product. The solvent evaporated in the drying chamber is recovered in a condenser for reuse/disposal. The uncontrolled emissions are vented through two carbon adsorber beds in series.**
4.	Manufacturer: **Niro/GEA**
5.	Model:
6.	Serial Number: **093-1993-00**

Raw Material Information

7. Raw Materials Used in Process

If there are more than four Raw Materials used, attach additional copies of this page as needed.

Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1. Isopropanol	67-63-0	117 kg/yr average	YES X NO
7.2. Ethyl Acetate	141-78-6	117 kg/yr average	YES X NO
7.3. Methylene Chloride	75-09-2	1168 kg/yr average	YES X NO
7.4. Tetrahydrofuran	109-99-9	117 kg/yr average	YES X NO

Products Produced Information

8. Products Produced

If there are more than four Products Produced, attach additional copies of this page as needed.

Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.			☐ YES ☐ NO
8.2.			☐ YES ☐ NO

Products Produced Information

8.3.			☐ YES ☐ NO
8.4.			☐ YES ☐ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Product Produced.

Byproducts Generated Information

9. Byproducts Generated

If there are more than four Byproducts Generated, attach additional copies of this page as needed.

	Byproduct Generated	CAS Number	Generation Rate (include units)	MSDS Attached?
9.1.				☒ YES ☐ NO
9.2.				☐ YES ☐ NO
9.3.				☐ YES ☐ NO
9.4.				☐ YES ☐ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Byproduct Generated.

General Information

10. Manufacturer's Rated Capacity or Maximum Throughput of Equipment or Process: **Maximum run rate cannot exceed 4 kg/hr**

11. Describe Important Manufacturer Specifications and/or Operating Parameters for Equipment or Process: **See attached**

Attach the Manufacturer's Specification Sheet(s) for the equipment or process.

Control Device Information

12. Is an Air Pollution Control Device Used? ☒ YES ☐ NO

If an Air Pollution Control Device is used, complete the rest of Question 12. If not, proceed to Question 13.

12.1. Is Knockout Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.11 and attach it to this application.

12.2. Is a Settling Chamber Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.10 and attach it to this application.

12.3. Is an Inertial or Cyclone Collector Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.5 and attach it to this application.

12.4. Is a Fabric Collector or Baghouse Used? ☐ YES ☒ NO

Control Device Information

If YES, complete Form AQM-4.6 and attach it to this application.

12.5. Is a Venturi Scrubber Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.8 and attach it to this application.

12.6. Is an Electrostatic Precipitator Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.7 and attach it to this application.

12.7. Is Adsorption Equipment Used? ☒ YES ☐ NO

If YES, complete Form AQM-4.2 and attach it to this application.

12.8. Is a Scrubber Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.4 and attach it to this application.

12.9. Is a Thermal Oxidizer or Afterburner Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.1 and attach it to this application.

12.10. Is a Flare Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.3 and attach it to this application.

12.11. Is Any Other Control Device Used? ☐ YES ☒ NO

If YES, attach a copy of the control device Manufacturer's Specification Sheet(s).

If any other control device is used, complete the rest of Question 12. If not, proceed to Question 13.

12.12. Describe Control Device:

12.13. Pollutants Controlled: ☐ VOCs ☐ HAPs ☐ PM ☐ PM_{10} ☐ $PM_{2.5}$ ☐ NO_X ☐ SO_X ☐ Metals ☐ Other (Specify):

12.14. Control Device Manufacturer:

12.15. Control Device Model:

12.16. Control Device Serial Number:

12.17. Control Device Design Capacity:

12.18. Control Device Removal or Destruction Efficiency:

Stack Information

13. How Does the Process Equipment Vent:
(check all that apply)
☐ Directly to the Atmosphere
☒ Through a Control Device Covered by Forms AQM-4.1 through 4.12
☐ Through Another Control Device Described on This Form

If any of the process equipment vents directly to the atmosphere or through another control device described on this form, proceed to Question 14. If the process equipment vents through a control device, provide the stack parameters on the control device form and proceed to Question 18.

14. Number of Air Contaminant Emission Points: **1**

If there are more than three Emission Points, attach additional copies of this page as needed.

For the first Emission Point

Stack Information

15.	Emission Point Name: **R&D Spray Dryer**
15.1.	Stack Height Above Grade: **10 feet**
15.2.	Stack Exit Diameter: **0.333 feet** *(Provide Stack Dimensions If Rectangular Stack)*
15.3.	Is a Stack Cap Present? ☐ YES ☒ NO
15.4.	Stack Configuration: ☐ Vertical ☐ Horizontal ☒ Downward-Venting *(check all that apply)* ☐ Other (Specify):
15.5.	Stack Exit Gas Temperature: **20 °C**
15.6.	Stack Exit Gas Flow Rate: **29.7 ACFM**
15.7.	Distance to Nearest Property Line: **362 feet**
15.8.	Describe Nearest Obstruction: **Building 8162**
15.9.	Height of Nearest Obstruction: **32 feet**
15.10.	Distance to Nearest Obstruction: **about 10 feet**
15.11.	Are Stack Sampling Ports Provided? ☐ YES ☒ NO
For the second Emission Point. If there is no second Emission Point, proceed to Question 18.	
16.	Emission Point Name:
16.1.	Stack Height Above Grade: **feet**
16.2.	Stack Exit Diameter: **feet** *(Provide Stack Dimensions If Rectangular Stack)*
16.3.	Is a Stack Cap Present? ☐ YES ☐ NO
16.4.	Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting *(check all that apply)* ☐ Other (Specify):
16.5.	Stack Exit Gas Temperature: **°F**
16.6.	Stack Exit Gas Flow Rate: **ACFM**
16.7.	Distance to Nearest Property Line: **feet**
16.8.	Describe Nearest Obstruction:
16.9.	Height of Nearest Obstruction: **feet**
16.10.	Distance to Nearest Obstruction: **feet**
16.11.	Are Stack Sampling Ports Provided? ☐ YES ☐ NO
For the third Emission Point. If there is no third Emission Point, proceed to Question 18.	
17.	Emission Point Name:
17.1.	Stack Height Above Grade: **feet**
17.2.	Stack Exit Diameter: **feet** *(Provide Stack Dimensions If Rectangular Stack)*
17.3.	Is a Stack Cap Present? ☐ YES ☐ NO
17.4.	Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting *(check all that apply)* ☐ Other (Specify):
17.5.	Stack Exit Gas Temperature: **°F**

Stack Information

17.6. Stack Exit Gas Flow Rate:	**ACFM**
17.7. Distance to Nearest Property Line:	**feet**
17.8. Describe Nearest Obstruction:	
17.9. Height of Nearest Obstruction:	**feet**
17.10. Distance to Nearest Obstruction:	**feet**
17.11. Are Stack Sampling Ports Provided?	☐ YES ☐ NO

Monitoring Information

18. Will Emissions Data be Recorded by a Continuous Emission Monitoring System?	☐ YES ☒ NO
If Yes, attach a copy of the Continuous Emission Monitoring System Manufacturer's Specification Sheets	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.1. Pollutants Monitored: ☐ VOCs ☐ HAPs ☐ PM ☐ PM_{10} ☐ $PM_{2.5}$ ☐ NO_X ☐ SO_X ☐ Metals ☐ Other (Specify):	
18.2. Describe the Continuous Emission Monitoring System:	
18.3. Manufacturer:	
18.4. Model:	
18.5. Serial Number:	
18.6. Will Multiple Emission Units Be Monitored at the Same Point?	☐ YES ☐ NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.7. Emission Units Monitored:	
18.8. Will More Than One Emission Unit be Emitting From the Combined Point At Any Time?	☐ YES ☐ NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.9. Emission Units Emitting Simultaneously:	

Voluntary Emission Limitation Request Information

19. Are You Requesting Any Voluntary Emission Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ☒ NO
If YES, complete the rest of Question 19. If NO, proceed to Question 20.	
19.1. Describe Any Requested Emission Limitations:	

Voluntary Operating Limitation Request Information

Voluntary Operating Limitation Request Information	
20. Are You Requesting Any Voluntary Operating Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ☒ NO
If YES, complete the rest of Question 20. If NO, proceed to Question 21.	
20.1. Describe Any Requested Operating Limitations:	

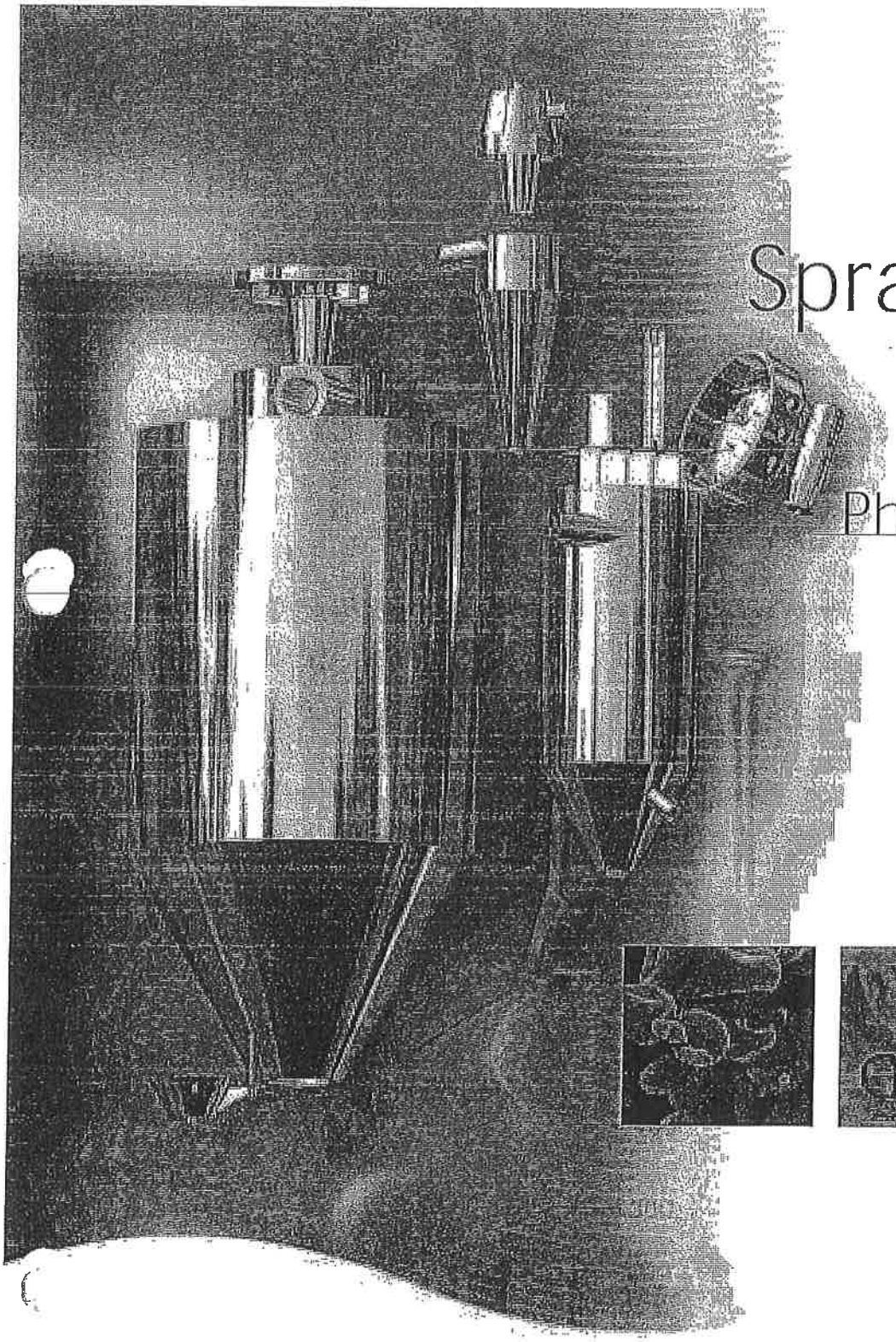
Additional Information	
21. Is There Any Additional Information Pertinent to this Application?	☐ YES ☒ NO
If YES, complete the rest of Question 21.	
21.1. Describe:	

GEA

Process Engineering
Division

Niro Pharma Systems

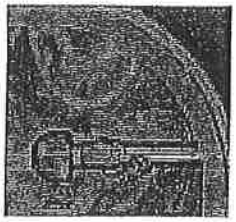
AEROMATIC BUCK COLLETTE COURTOY FIELDER NICA NIRO

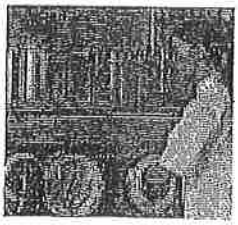


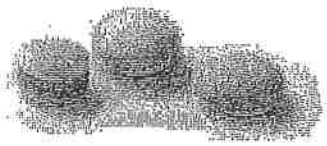
Niro Spray Dryers

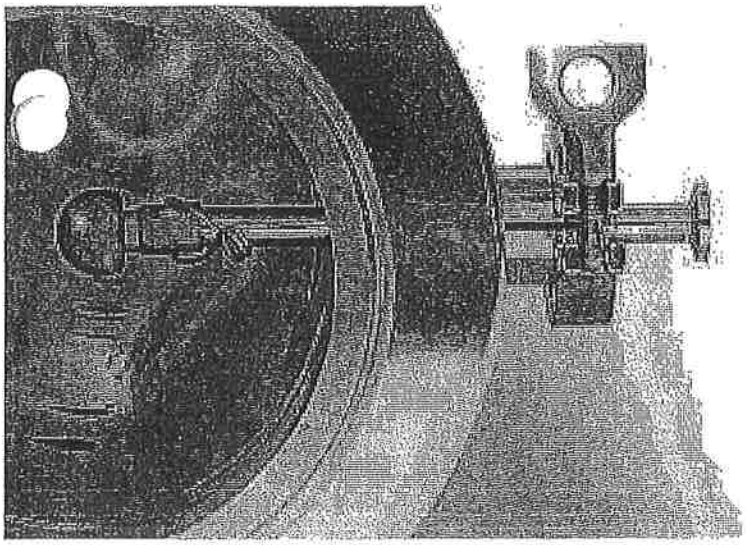
for the Pharmaceutical Industry

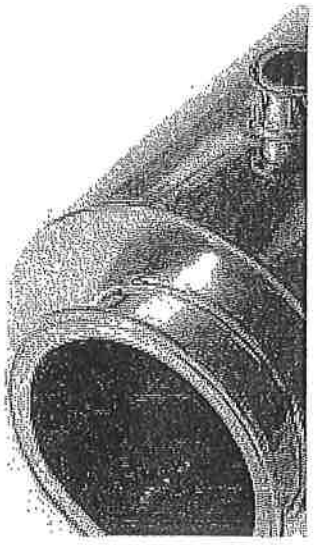
- Flexible
- Scalable
- Reliable
- Controllable







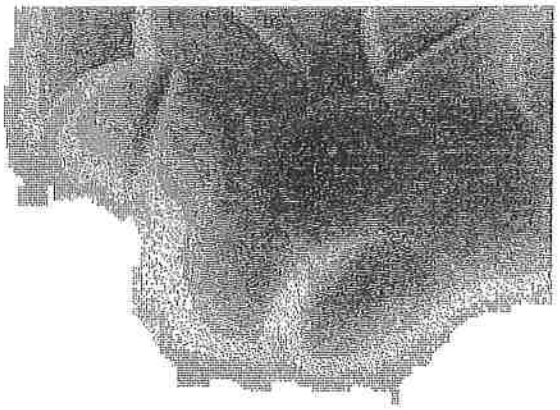




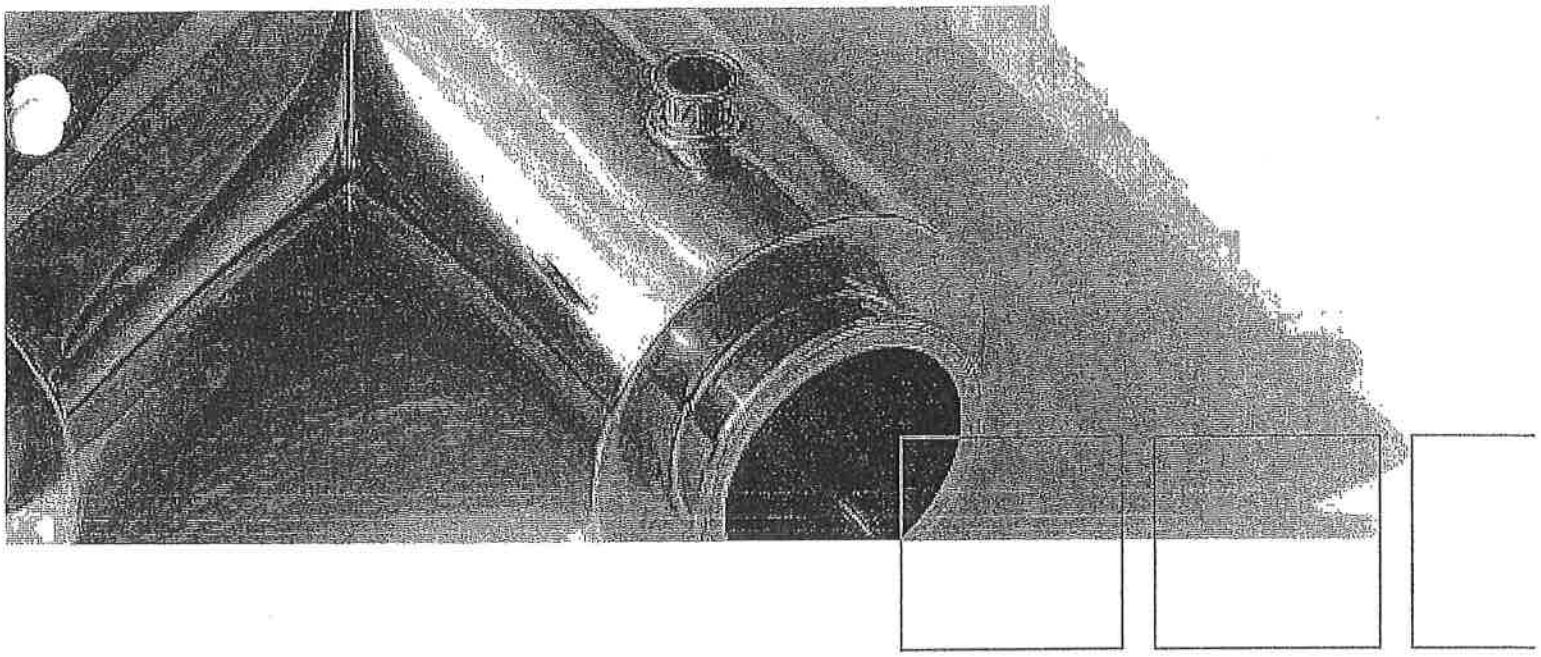
For over half a century, Niro has supplied drying plants for powders and particulates to the pharmaceutical industry. This includes a small capacity dryers designed for R & D as well as industrial size plants for continuous production of pharmaceutical compounds under cGMP conditions.

Product Know-How

– Process Expertise



Our plant and process expertise is based on experience and R & D. With plants installed around the world and literally thousands of tests performed, we have established a solid base of expertise related to the needs of the pharmaceutical manufacturing industry.



Delivering the Right Solutions

Every Niro plant begins with the customer's desire to create a product that will succeed in the market. In Niro, the customer finds a partner who will assist him to meet that goal. Our expertise includes primary as well as secondary pharmaceuticals, including technologies for processing Active Pharmaceutical Ingredients using spray drying, agglomeration, encapsulation, and spray congealing.

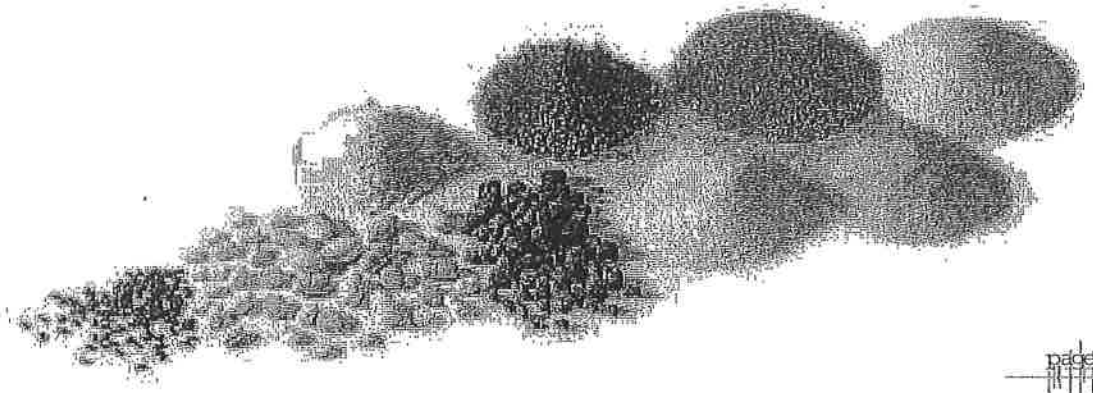
Plants Customized for Success

Every pharmaceutical plant and system from Niro is a unique union of proven technology and individual solutions. Based on standard components, we supply plants for cGMP production configured to meet the customer's specific requirements.

Among the large number of variations are: The right size to meet the customer's output requirements, the drying principle to be used, atomization configuration, and open or closed cycle operation.

A Partnership in Every Perspective

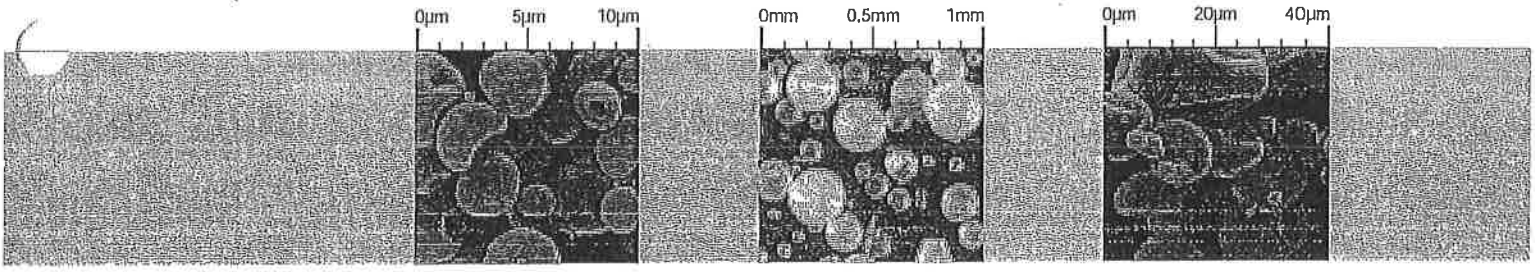
Working with Niro means entering a solid partnership every step of the way, from process testing and design to specification of the software controlling your new plant. And our comprehensive after sales program ensures that your return on investment is optimized throughout the lifetime of the plant.



Primary Pharmaceuticals

Active Pharmaceutical Ingredients (API) are typically produced by extraction or chemical syntheses. In most cases, the material is subsequently crystallized, mechanically separated, and dried. These steps can often be replaced by spray drying, which not only allows the customer to control the moisture or residual solvent content in the powder but also to create materials with a tailor-maid particle size distribution, morphology, and nature.

Secondary Pharmaceuticals



Powders for Inhalation

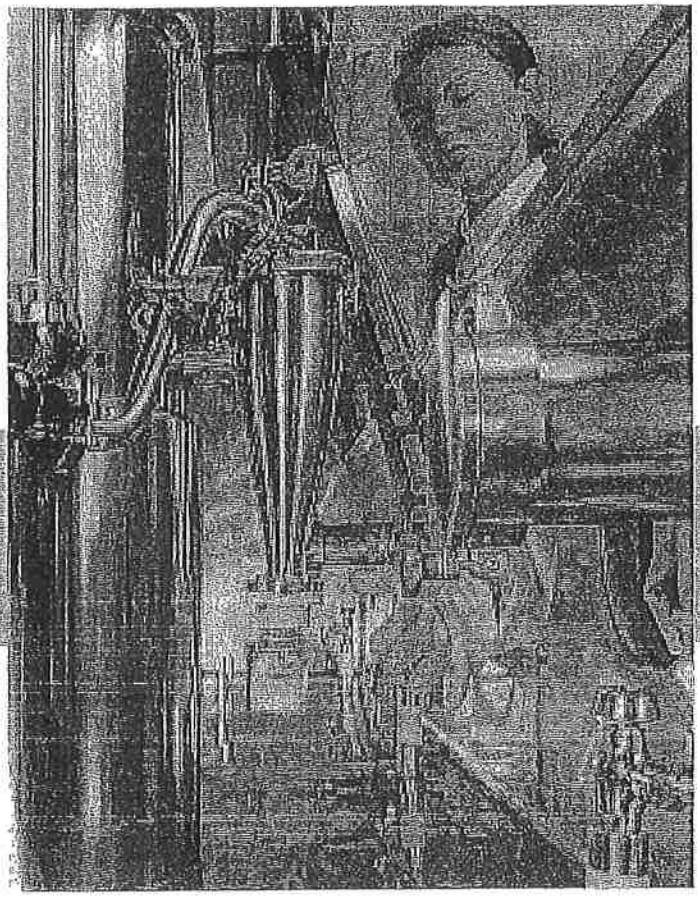
Spray drying has become the method of choice for the preparation of fine particles for inhalation. The spray dryer must be equipped with a special atomization device to produce the very fine droplets and a device for fine particle collection.

Encapsulation

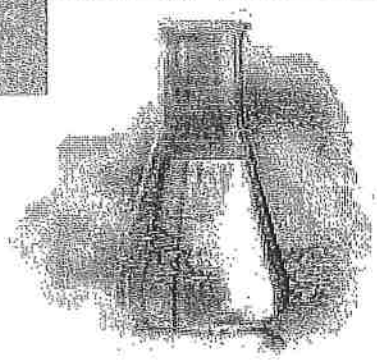
One way to achieve a constant drug level in a patient's body is to encapsulate the API in a biodegradable polymer. Controlled by diffusion, the drug is released at a constant rate over a prolonged period of time. To prepare such particles by spray drying, API and polymer are brought into solution and spray dried. Alternatively, spray congealing techniques can be used.

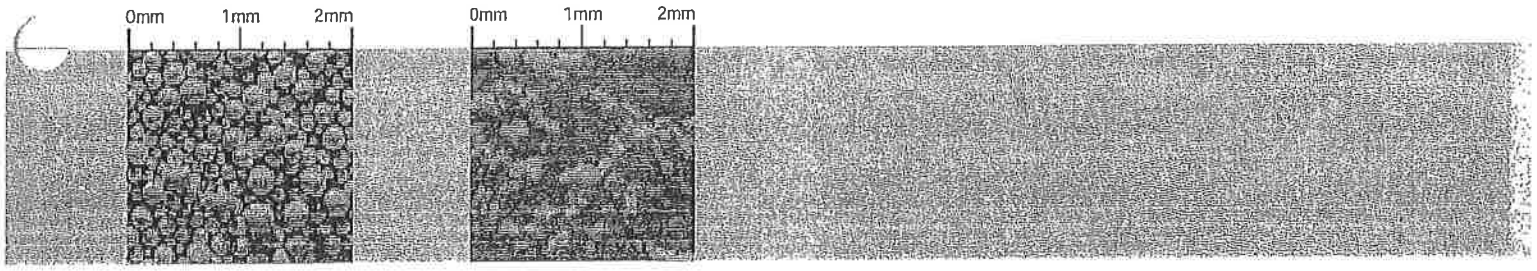
Increased Bioavailability

Some modern molecules can have a poor solubility in water or body fluids. Thus it takes an extremely long time for the API crystals to dissolve and for the drug concentration to reach the required level. If the drug product is given orally, the dissolution rate may be increased effectively by keeping the spray dried API in amorphous form using a polymer.



S D Micro™ mounted in glove box.
Spray dryer for drying very small quantities of feeds containing organic solvents





Spray Congealing

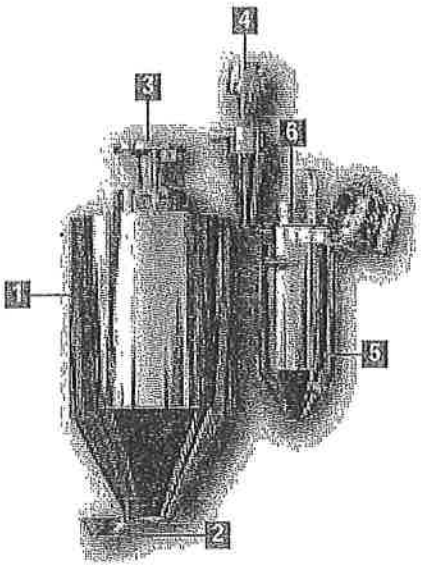
As an alternative to "classic" pharmaceutical production, it is possible to melt the active together with a polymer to enhance bioavailability. As an alternative only the polymer is molten and the active is incorporated just before atomization. The mix is then sprayed into cold process gas. This process can form a matrix in which the release can be easily controlled by the selection of the process conditions without the need for an additional coating step.

Directly Compressible

Until now, a separate granulation step has often been required in the production of solid dosage forms. The granulate is needed to avoid segregation and to assure flow properties so the dyes of a high-speed tablet press can be filled accurately. With the Fluidized Spray Dryer - FSD™ or IFD™ - concept the granulation step can be an integrated part of the continuous drying process. The FSD™ technology can also be used to achieve a low residual volatiles content in the final spray dried powder.

Sterile Excipients

Production of dry sterile dosage forms often involves large-scale mixing of the API with one or more excipients. To achieve a homogeneous mixture, the particle size distribution of the excipient(s) must match that of the API. In a one-step-operation, spray drying can turn a sterile solution of the excipient into sterile particles of the required size with no risk of introducing impurities — a well-known problem if milling is used.



Spray Drying

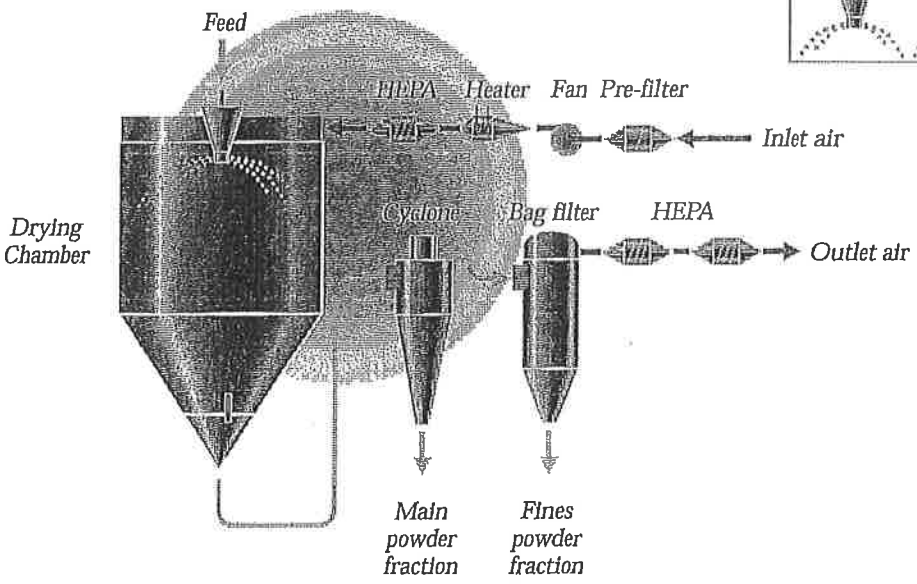
Standardized Customization

Today's increased demands for customized design, special materials of construction, special surface treatment, advanced control systems, GMP production, and process validation have resulted in continuous improvement in spray dryer design for the pharmaceutical industry.

Atomization and Powder Discharge
One of the most important choices in a plant configuration is choosing the right atomization and powder discharge method. We offer a wide range of solutions as illustrated below and to the right.

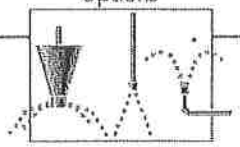
1. **Spray dryer chamber**
2. **Swirl cone**
3. **Gas/air disperser**
4. **Cyclone**
5. **Bag filter**
6. **Filter bag cages**

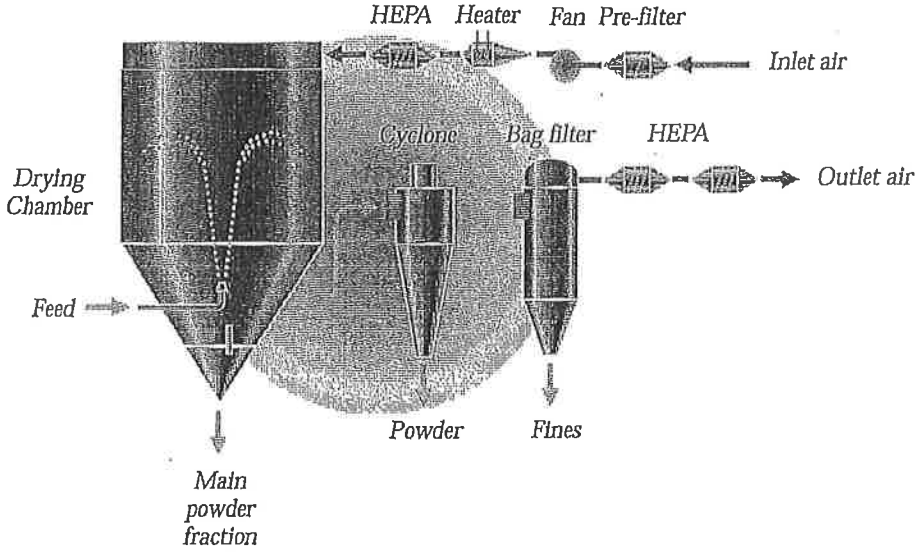
Single Point Discharge



Two Point Discharge

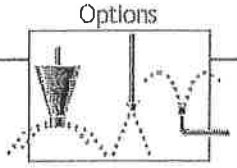
Atomizer/Nozzle Options

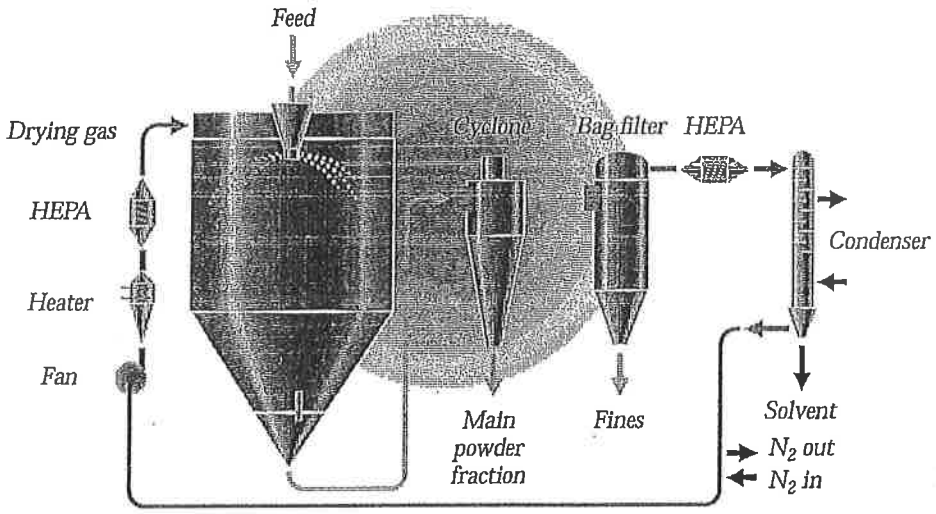




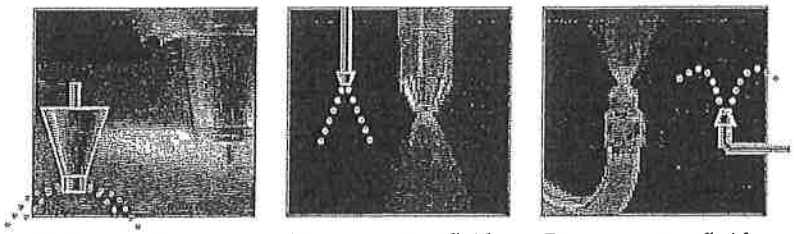
Closed Cycle Design

Atomizer/Nozzle Options





Atomizer/Nozzle Options



Rotary atomizer

Pressure or two-fluid nozzle, co-current mode

Pressure or two-fluid nozzle, fountain mode

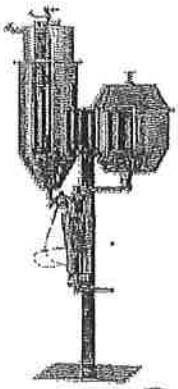
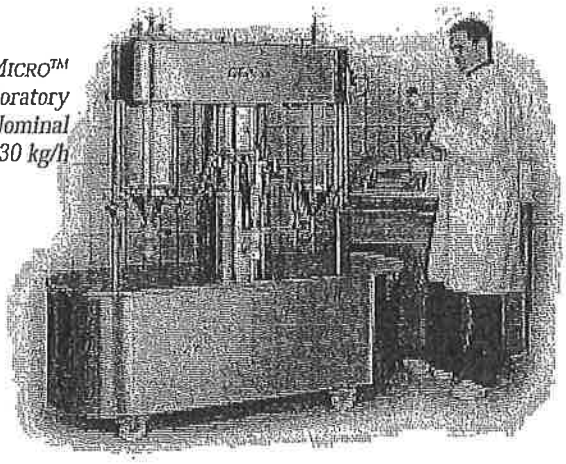


Table top aseptic spray dryer - ASEPTICSD™ Nominal drying gas rate: 30 kg/h



SDMICRO™ R&D and laboratory spray dryer. Nominal drying gas rate: 30 kg/h

PHARMASD™

Meeting Every Requirement

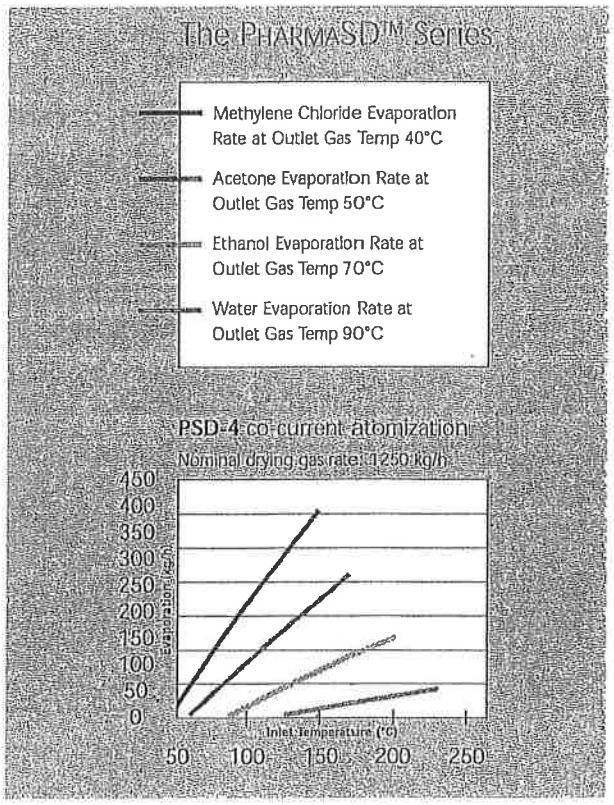
To meet the high requirements from the pharmaceutical industry, Niro has developed a series of spray dryers, the PHARMASD™ (PSD).

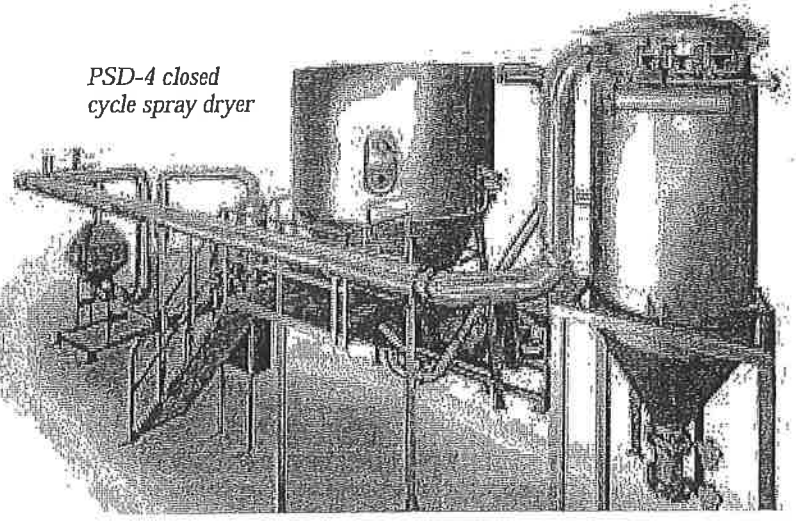
Tailor-Made Standard

The philosophy behind the design is that a combination of standardized modules are built together in order to meet the requirement for a specific duty. Therefore, dryers of equal capacity may be completely different with respect to design, configuration and physical size.

Spray Drying Organic Solvents

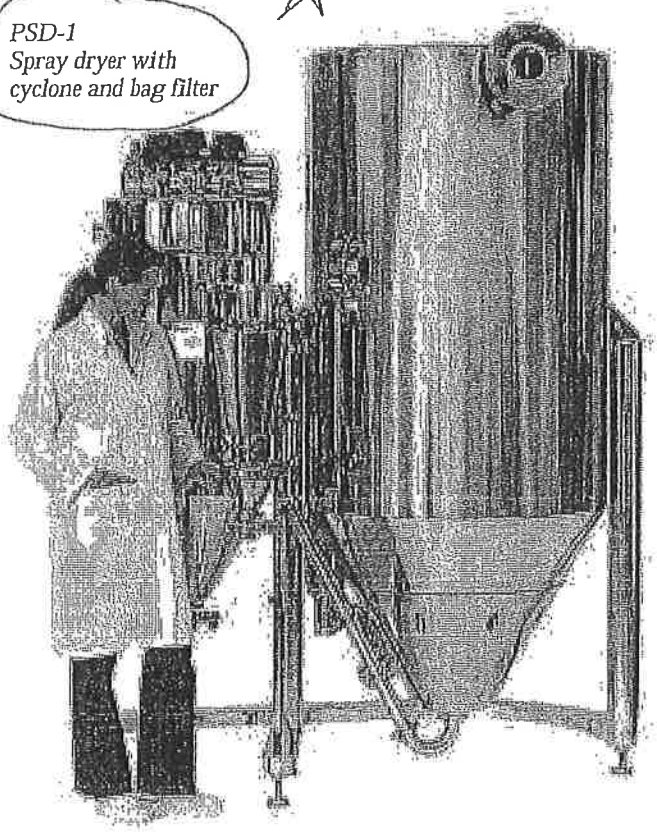
The use of solvents when preparing pharmaceutical ingredients poses a challenge in the drying process and has resulted in the use of nitrogen as a drying gas. Our spray dryers are configured for drying of compounds that are based on acetone, methylene, chloride, ethanol, and other organic solvents. The drying parameters and capacity vary greatly, depending on the solvent used, as shown in the tables below.

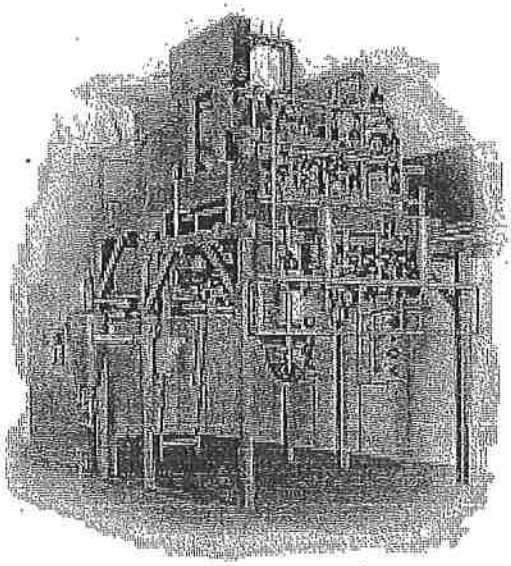




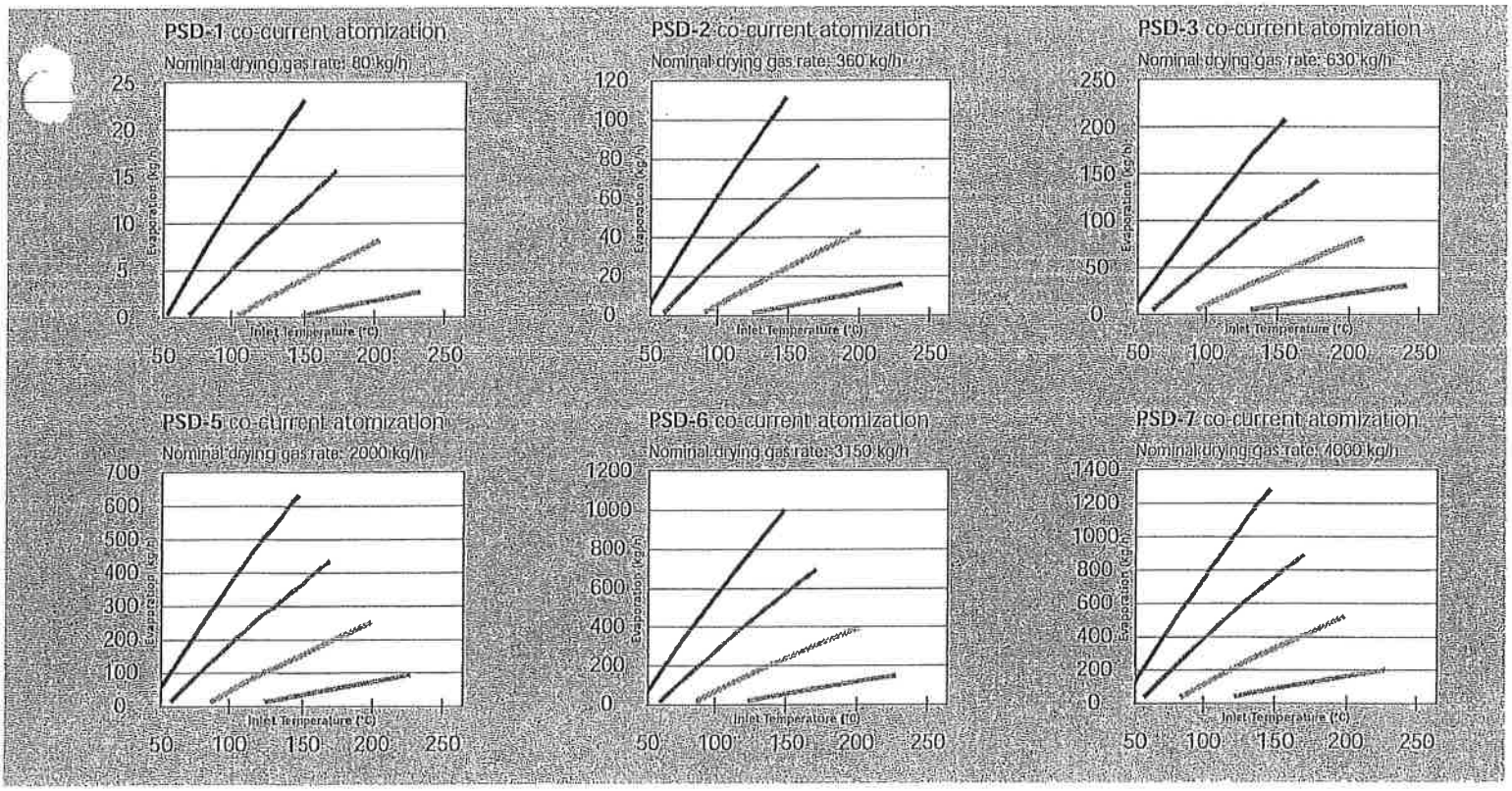
PSD-4 closed cycle spray dryer

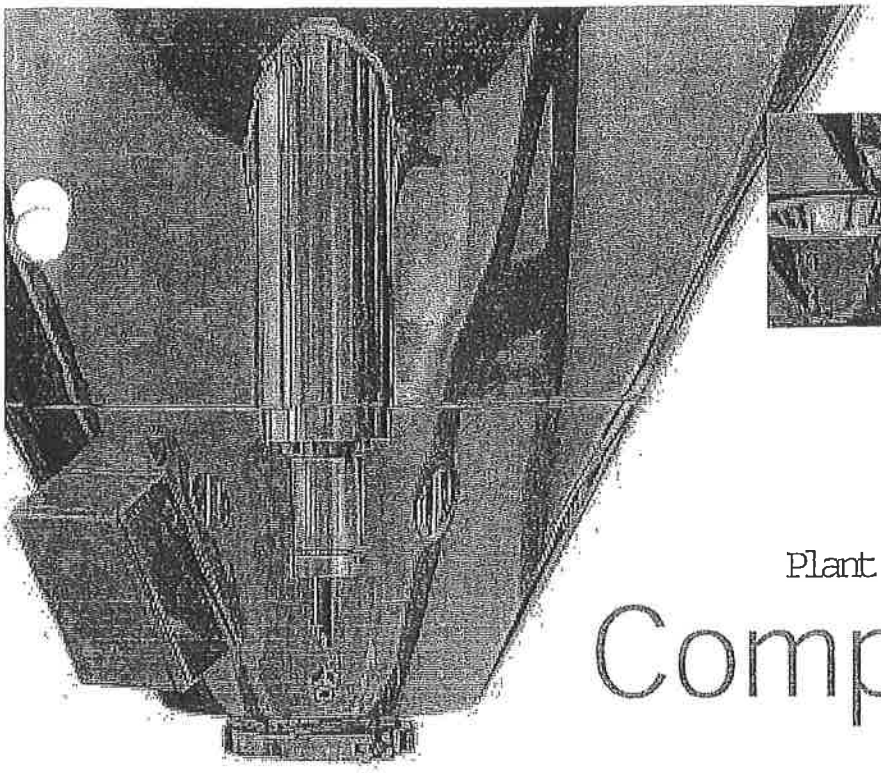
PSD-1
Spray dryer with cyclone and bag filter

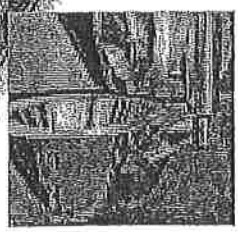


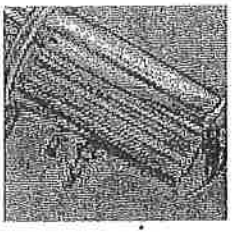


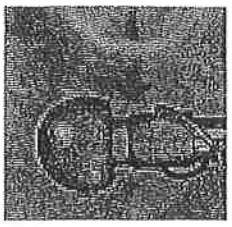
PSD-2
Spray dryer equipped with steam sterilization



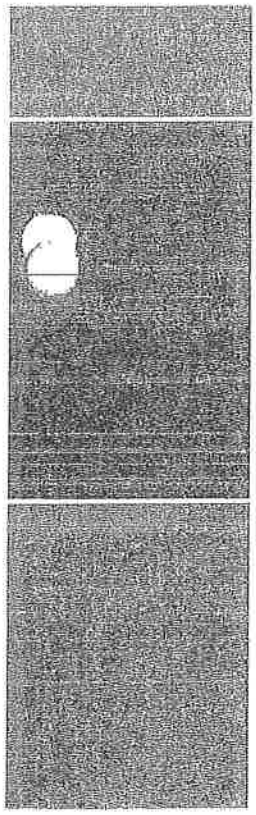








Plant Components

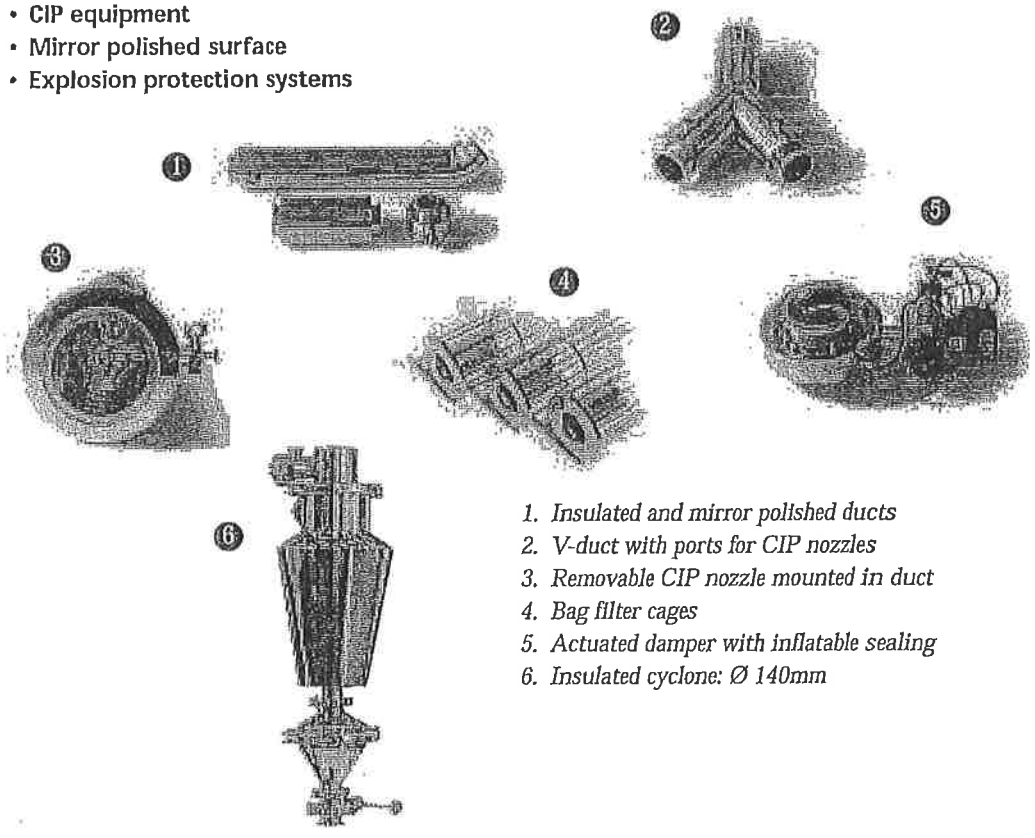


PHARMASD™ design options include:

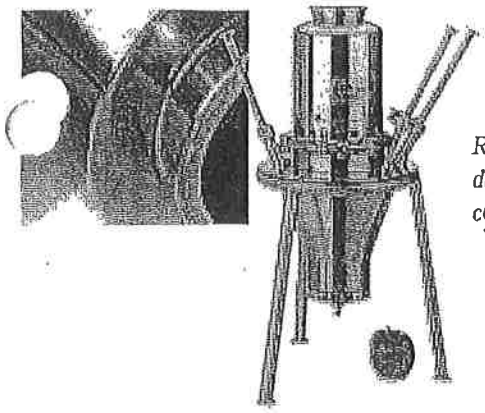
- Equipment for closed-cycle operation
- Facilities for hot gas sanitization
- Special sanitary duct connections
- Special construction materials
- HEPA filters for gas streams
- Special process gas disperser design
- Swirl cone for chamber access
- CIP equipment
- Mirror polished surface
- Explosion protection systems

Single-unit manufacturing combined with the sue of standard modules has replaced serial plant production withing the pharmaceutical industry, enabling truly customized solutions based on proven systems.

Each module, indeed each system component, must meet the strictest requirements and regulatory standards around the world.



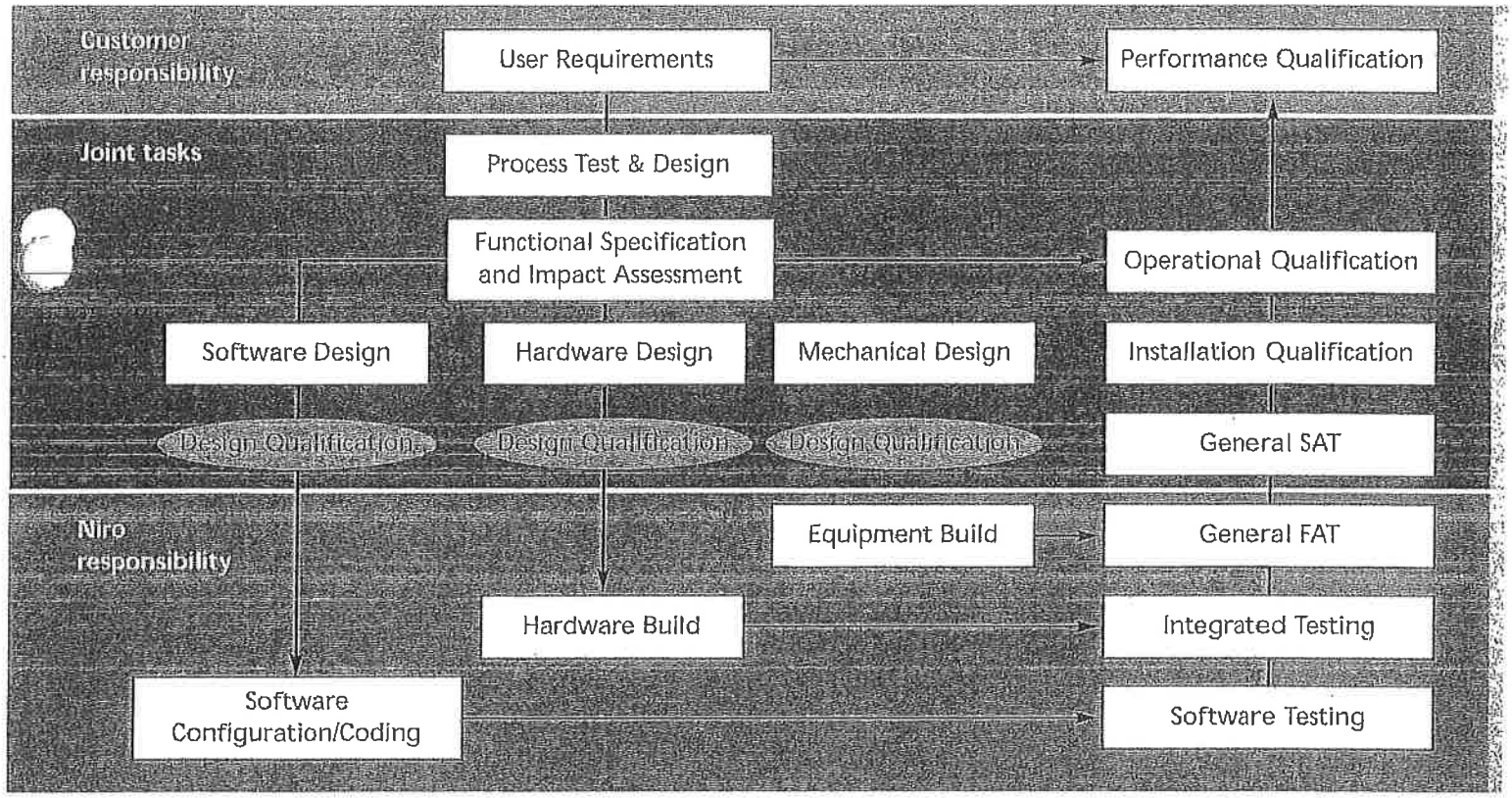
1. *Insulated and mirror polished ducts*
2. *V-duct with ports for CIP nozzles*
3. *Removable CIP nozzle mounted in duct*
4. *Bag filter cages*
5. *Actuated damper with inflatable sealing*
6. *Insulated cyclone: Ø 140mm*



Rotary atomizer F1.5 X designed to meet cGMP requirements

The Complete Partnership

Working with You...
Entering a partnership with Niro means entering a partnership that does not end until you are completely satisfied. From the moment you have specified your user requirements and until the plant has been put into service and has been qualified, our trained staff stays with you at every step of the process, working in close co-operation with your own staff creating the components and systems that will result in a finished plant.

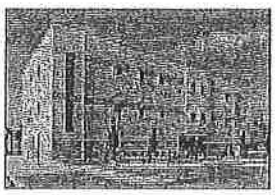


Every Step of the Way
Based on years of experience, equipment qualification will be carried out according to an agreed plan using documents prepared by Niro.

Our engineers will contribute to a successful qualification of the equipment in close co-operation with your validation staff.

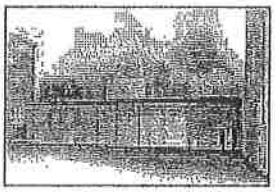
Niro Pharma Systems

AEROMATIC BUCK COLLETTE COURTOY FIELDER NICA NIRO



Niro Pharmaceutical Technology Centre

USA: Coating and drying technology

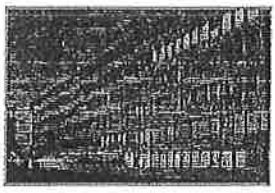


Niro Pharmaceutical Test Station

Denmark: Spray drying technology

NPS Technology Center

Switzerland: Solid dosage technology



Niro A/S

Denmark

Niro Pharma Systems is world leader in providing advanced processing solutions for solid dosage forms to the pharmaceutical industry. Based on a dedication to research and durable quality, Niro Pharma Systems offers a wide range of solutions, from individual pieces of equipment to complete integrated plants, by uniting the state-of-the-art technologies of Aeromatic, Buck, Collette, Courtoy, Fielder, Nica and Niro.

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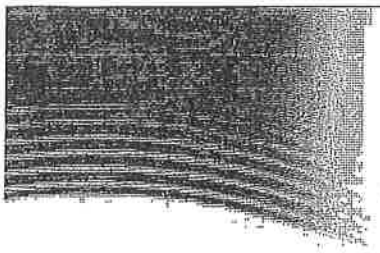
WWW.NIROINC.COM



GEA Process Engineering Division

Niro Pharma Systems

A company of mg technologies group

PSD-1

GEA
Process Engineering
Division

Niro Inc.

SPECIFICATION
FOR
MOBILE MINOR SPRAY DRYER

1. CO-CURRENT TWO-FLUID NOZZLE ATOMIZER, externally mixing, two-fluid nozzle to be mounted in the roof of the drying chamber. The nozzle lance, body, orifice, and air cap are fabricated in stainless steel, type AISI 316. The system is supplied with a 0.5mm orifice, fittings for the air hose connection, air pressure regulator, and air flow meter.

   Compressed air must be supplied by the customer at 10 - 50 psig and a maximum of 8 scfm.

2. DRYING CHAMBER with an inside diameter of 0.8 meters and is insulated with approximately 40 mm of Rockwool covered with a stainless steel outer shell. The chamber is provided with an interior light, observation pane for inspection during operation, and one rapping stud. The rapping stud is very useful in applications where sticky materials may attempt to build up in the chamber. The interior is made of stainless steel, type AISI 316. The exterior is stainless steel, type AISI 304. The roof of the drying chamber is made of stainless steel, type AISI 316, inside, and stainless steel, type AISI 304, outside. The entire roof can be lifted, using a special pneumatic lifting device and also tilts for ease of cleaning.

3. AIR DISPERSER made of stainless steel, type AISI 304, is built into the roof and specially designed to produce the desired air flow pattern necessary for proper drying of the atomized droplets.

4. AIR DUCTS made of stainless steel, type AISI 316, are provided with quick-release threaded fasteners, to ensure easy dismantling for ease of cleaning.

5. CYCLONE made of stainless steel, type AISI 316, is designed for maximum collection efficiency and ease of cleaning. The product is collected in a one liter glass jar, threaded to the cyclone discharge.

6. EXHAUST FAN made of silumin and is driven by a direct coupled, three (3) phase squirrel cage motor, 0.5 kW. The fan is rated for an air flow of 80 kg/hr (40 cfm).

7. AIR HEATER, 10.0 kW, infinitely variable. Maximum inlet air temperature is approximately 350°C.

8. INSTRUMENT PANEL includes inlet air temperature controller, outlet air temperature indicator, and a switch for starting the fan and obtaining the base load for the electric air heater. The control panel is mounted on a mobile stand with the exhaust fan.

9. SUPPORTING STRUCTURE made of stainless steel, type AISI 304, with rubber castors for unit mobility.

10. SPARE PARTS

- one set of gaskets for cyclone and air ducts.
- one powder collecting jar.
- one filter for inlet air heater.

11. TOOLS for air duct connections.

Electrical Requirements:	230/460 Volt - 3 Ph - 60 Hz
Shipping Volume:	4.0 cubic meters (135 ft)
Gross Weight:	550 kg
Net Weight:	300 kg

Emissions Information Application

If you are using this form electronically, press F1 at any time for help

Process Information	
1.	Number of Individual Pieces of Process Equipment in Process: **1 - R&D Spray Dryer**
2.	Number of Individual Control Devices in Process: **1 - Carbon Beds**

Emissions Information for First Emission Point/Stack

3. Emission Point Name: **R&D Spray Dryer**

4. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack: **R&D Spray Dryer**

5. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 5.10 through 5.18)	CAS Number (Not required for 5.1 through 5.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
5.1.	Particulate Matter (PM)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.2.	PM_{10}		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.3.	$PM_{2.5}$		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.4.	Sulfur Oxides (SO_X)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.5.	Nitrogen Oxides (NO_X)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.6.	Carbon Monoxide (CO)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.7.	Total Volatile Organic Compounds (VOCs)		**0.86 lbs/hour**	**0.09 lbs/hour**	**1.26** tons/year	**0.127** tons/year
5.8.	Total Hazardous Air Pollutants (HAPs)		**1.47 lbs/hour**	**0.15 lbs/hour**	**2.14** tons/year	**0.215** tons/year

Emissions Information for First Emission Point/Stack

5.9.	CO_2		0 lbs/hour	lbs/hour	tons/year	tons/year
5.10.	CO_{2e}		0 lbs/hour	lbs/hour	tons/year	tons/year
5.11.			lbs/hour	lbs/hour	tons/year	tons/year
5.12.			lbs/hour	lbs/hour	tons/year	tons/year
5.13.			lbs/hour	lbs/hour	tons/year	tons/year
5.14.			lbs/hour	lbs/hour	tons/year	tons/year
5.15.			lbs/hour	lbs/hour	tons/year	tons/year

6. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Second Emission Point/Stack

7. Emission Point Name:

8. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

9. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 9.10 through 9.18)	CAS Number (Not required for 9.1 through 9.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
9.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
9.2.	PM_{10}		lbs/hour	lbs/hour	tons/year	tons/year
9.3.	$PM_{2.5}$		lbs/hour	lbs/hour	tons/year	tons/year

Emissions Information for Second Emission Point/Stack

9.4.	Sulfur Oxides (SO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.5.	Nitrogen Oxides (NO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.6.	Carbon Monoxide (CO)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.7.	Total Volatile Organic Compounds (VOCs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.8.	Total Hazardous Air Pollutants (HAPs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.9.	CO_2		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.10.	CO_{2e}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.11.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.13.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.14.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.15.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

10. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Third Emission Point/Stack

11. Emission Point Name:

12. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

13. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

Emissions Information for Third Emission Point/Stack

	Pollutant Name (Specify VOCs and HAPs Individually in 13.10 through 13.18)	CAS Number (Not required for 13.1 through 13.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
13.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.4.	Sulfur Oxides (SO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.5.	Nitrogen Oxides (NO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.6.	Carbon Monoxide (CO)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.7.	Total Volatile Organic Compounds (VOCs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.8.	Total Hazardous Air Pollutants (HAPs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.9.	CO_2		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.10.	CO_{2e}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.11.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.13.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.14.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.15.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

14. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Fourth Emission Point/Stack

15. Emission Point Name:

16. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

17. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 17.10 through 17.18)	CAS Number (Not required for 17.1 through 17.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
17.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.4.	Sulfur Oxides (SO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.5.	Nitrogen Oxides (NO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.6.	Carbon Monoxide (CO)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.7.	Volatile Organic Compounds (VOCs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.8.	Total Hazardous Air Pollutants (HAPs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.9.	CO_2		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.10.	CO_{2e}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.11.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.13.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.14.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.15.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

Emissions Information for Fourth Emission Point/Stack

18. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

If there are more than four Emission Points/Stacks, attach additional copies of this form as needed.

Overall Process Emissions

19. Pollutant Emissions

If more than 15 pollutants are emitted from this Process, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 19.10 through 19.18)	CAS Number (Not required for 19.1 through 19.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
19.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.4.	Sulfur Oxides (SO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.5.	Nitrogen Oxides (NO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.6.	Carbon Monoxide (CO)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.7.	Total Volatile Organic Compounds (VOCs)		**0.86 lbs/hour**	**0.09 lbs/hour**	**1.26** tons/year	**0.127** tons/year
19.8.	Total Hazardous Air Pollutants (HAPs)		**1.47 lbs/hour**	**0.15 lbs/hour**	**2.14** tons/year	**0.215** tons/year
19.9.	CO_2		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.10.	CO_{2e}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

Overall Process Emissions

19.13.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.14.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.15.		**lbs/hour**	**lbs/hour**	tons/year	tons/year

20. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Minor New Source Review Information

21. Does the Process Have the Potential to Emit More Than Five Tons Per Year of Any Pollutant? ☐ YES ☒ NO

22. Is the Source New or Existing? ☒ NEW ☐ EXISTING
See Question 11 of AQM-1

If the Process has the Potential to Emit more than five tons per year of any pollutant, and is a New Source, a Control Technology Analysis pursuant to Regulation No. 1125 Section 4 must be conducted and attached to this application.

Major New Source Review Information

23. Does the Process Have the Potential to Emit More Than the Significance Level for Any Pollutant? *(Check All That Apply)*

- ☐ Greater Than 25 Tons Per Year of Particulate Matter (PM)
- ☐ Greater Than 15 Tons Per Year of PM_{10}
- ☐ Greater Than 10 Tons Per Year of $PM_{2.5}$
- ☐ Greater Than 40 Tons Per Year of Sulfur Dioxide(SO_2)
- ☐ Greater Than 25 Tons Per Year of Nitrogen Oxides (NO_X) in New Castle and Kent County
- ☐ Greater Than 100 Tons Per Year of Nitrogen Oxides (NO_X) in Sussex County
- ☐ Greater Than 100 Tons Per Year of Carbon Monoxide (CO)
- ☐ Greater Than 25 Tons Per Year of Total Volatile Organic Compounds (VOCs) in New Castle and Kent County
- ☐ Greater Than 50 Tons Per Year of Total Volatile Organic Compounds (VOCs) in Sussex County
- ☐ Greater Than 75,000 Tons Per Year of Equivalent Carbon Dioxide (CO_{2e})

If the Process has the Potential to Emit greater than any of the amounts listed above 7 DE Admin. Code 1125 Sections 2 and/or 3 apply. Contact the Department at (302) 323-4542 or (302) 739-9402 for additional information

Additional Information

24. Is There Any Additional Information Pertinent to this Application? ☐ YES ☒ NO

If YES, complete the rest of Question 24.

24.1. Describe:

Maximum Emissions Calculations, R&D Spray Dryer (PSD1) with Condenser - Updated 10/23/15, Reviewed 5/17/2016

Run rate [1]	4	kg/hr	
Run Time [2]	10.0	hr/batch	
Solvent Used [3]	40	kg/batch/day	
Operating Days/yr [4]	292	days/yr	
Solvent Spray Dried	11680	kg/yr	
Max. venting gas rate [5]	12	kg/hr NITROGEN (rounded to the next whole value)	
Operating Hours	2,920	hr/yr	
Total Gas Vented [6]	35,040	kg/yr NITROGEN vented	

Typical Solvent Mix [9]	%	kg/yr Solvent (pre condenser)	Solvent Factor [7] (kg/kg)	Calculated kg/yr exhausted [8]	Maximum kg/yr exhausted (post condenser)	Maximum lb/hr exhausted (post condenser)*	Maximum tons/year exhausted (post condenser)	Annual Emissions as a 12 month rolling period (TPY)		% Solvent	kg/yr Solvent (pre condenser)	Calculated kg/yr exhausted	Max kg/yr exhausted (post condenser)	Max lb/hr exhausted (post condenser)	Max lb/hr exhausted (post carbon beds)
										Emissions with 100% of One Solvent					
Ethanol	17.0%	1,985.6	0.04	224.4	224.4	0.169	0.247	**0.025**		100%	11680	1,320.0	1,320.0	0.995	**0.099**
Methanol	35.0%	4,088.0	0.06	778.7	778.7	**0.587**	0.857	**0.086**		100%	11680	2,224.8	2,224.8	1.676	**0.168**
IPA	1.0%	116.8	0.03	11.0	11.0	0.008	0.012	**0.001**		100%	11680	1,104.6	1,104.6	0.832	**0.083**
Ethy Acetate	1.0%	116.8	0.14	50.0	50.0	0.038	0.055	**0.006**		100%	11680	5,004.5	5,004.5	3.771	**0.377**
Methylene Chloride	10.0%	1,168.0	0.41	1,427.2	1,168.0	0.880	1.285	**0.128**		100%	11680	14,271.9	11,680.0	8.800	**0.880**
THF	1.0%	116.8	0.22	77.3	77.3	0.058	0.085	**0.009**		100%	11680	7,733.8	7,733.8	5.827	**0.583**
Acetone	35.0%	4,088.0	0.28	3,375.3	3,375.3	**2.543**	3.713	**0.371**		100%	11680	9,643.8	9,643.8	7.266	**0.727**
	65%	**7,592.0**	-	**2,568.7**	**2,309.5**	**1.740**	**2.540**	0.126	VOCs						
						*1 kg = 2.2 lb		**0.214**	HAPs						

NOTES:

(1) Based on equipment design, the max run rate cannot exceed 4 kg/hr, typically it is run at 2 kg/hr to produce quality material

(2) The equipment runs in batches, one batch per day. In between batches the time for disassembly, cleaning, drying and assembly will take at least 14 hours. The max running time per batch per day is thus 24h minus 14 hours = 10 hours

(3) This is total maximum Kg = solvent + solids. To be conservative, consider it all solvent and do not adjust out the

(4) Approximately 20% of the time throughout the year between batches, the dryer is also not running because the spray dried material needs to be characterized for particle size, particle size distribution, density, solvent content and morphology. The max running days is thus calculated as follows: (365 days)*(100%-20%)=292 days

(5) MAXIMUM GAS VENTING RATE:

- The vent rate of each PSD1 dryer is up to 9.5 kg/hr atomizing gas (nominally 6.5 kg/hr), 1.25 kg /hr bag house pulse cleaning, and 1 kg/hr system pressure control (it would modulate in compensation for low /no atomizing gas).

Thus, maximum vent rate after the condenser total max 11.75 kg/hr (rounded to 12 above).

- Note: this is the required venting rate for non-condensable N2 to maintain pressure. Solvent vapor in the vented stream is in addition to the 11.75 kg/Hr.

(6) Ignores purging system gas inventory remaining at end of batch, which is negligibly small relative to solvent in the

(7) Solvent Factors:

Solvent	MW	Max Cond Temp, C	Vapor Pressure @ max cond temp, (mmHg)	vol % in N2 @ 1 ATM	Solvent Factor (kg solv/ kg N2 vented)
Ethanol	46.10	5	17	2.24	0.038
Methanol	32.00	5	40	5.26	0.063
Acetone	58.10	5	89	11.71	0.275
IPA	60.10	5	11	1.45	0.032
Ethy Acetate	88.10	5	33	4.34	0.143
Methylene Chloride	84.90	-10	90	11.84	0.407
THF	72.10	5	60	7.89	0.221

- Condenser temperatures indicated are the maximum required by the process tc meet desired process and product specifications.

- Vapor Pressure Data Ref: Table 3-8, Vapor Pressures of Organic Compounds, up to 1 ATM, Table 3-8, Vapor Pressures of Organic Compounds, up to 1 Atm Perry's Handbook, 5th ed.

(8) Calculation assumes gas is saturated at indicated maximum condenser temp.

(9) Typical solvent mix assumes the listed solvent is used an average % throughout the year

Expected Emissions Calculations, R&D Spray Dryer (PSD1) with Condenser - Updated 10/23/15, Reviewed 5/17/2016

Run rate [1]	2	kg/hr
Run Time [2]	8.0	hr/batch
Solvent Used [3]	16	kg/batch/day
Operating Days/yr [4]	182.5	days/yr
Solvent Spray Dried	2920	kg/yr
Max. venting gas rate [5]	12	kg/hr NITROGEN (rounded to the next whole value)
Operating Hours	1,460	hr/yr
Total Gas Vented [6]	17,520	kg/yr NITROGEN vented

Typical Solvent Mix [9]	%	kg/yr Solvent (pre condenser)	Solvent Factor [7] (kg/kg)	Calculated kg/yr exhausted [8]	Expected kg/yr exhausted (post condenser)	Expected lb/hr exhausted (post condenser)*	Expected tons/year exhausted (post condenser)	%	kg/yr Solvent (pre condenser)	Calculated kg/yr exhausted	Expected kg/yr exhausted (post condenser)	Expected lb/hr exhausted (post condenser)	Expected Emissions (lb/hr) after carbon beds
Ethanol	17.0%	496.4	0.04	112.2	112.2	0.169	0.123	100%	2920	660.0	660.0	0.995	0.099
Methanol	35.0%	1,022.0	0.06	389.3	389.3	0.587	0.428	100%	2920	1,112.4	1,112.4	1.676	0.168
IPA	1.0%	29.2	0.03	5.5	5.5	0.008	0.006	100%	2920	552.3	552.3	0.832	0.083
Ethyl Acetate	1.0%	29.2	0.14	25.0	25.0	0.038	0.028	100%	2920	2,502.3	2,502.3	3.771	0.377
Methylene Chloride	100.0%	2,920.0	0.41	7,135.9	2,920.0	4.400	3.212	100%	2920	7,135.9	2,920.0	4.400	0.440
THF	1.0%	29.2	0.22	38.7	29.2	0.044	0.032	100%	2920	3,866.9	2,920.0	4.400	0.440
Acetone	35.0%	1,022.0	0.28	1,687.7	1,022.0	1.540	1.124	100%	2920	4,821.9	2,920.0	4.400	0.440
	155%	**4,526.0**	-	**7,706.7**	**3,481.3**	**5.246**	**3.829**						
						*1 kg = 2.2 lb							

NOTES:

(1) Based on equipment design, the max run rate cannot exceed 4 kg/hr, typically it is run at 2 kg/hr to produce quality material.

(2) The equipment is runs in batches, one batch per day. In between batches the time for disassembly, cleaning, drying and assembly will take at least 14 hours. The actual run time is typically less than 8 hours.

(3) This is total maximum Kg = solvent + solids. To be conservative, consider it all solvent and do not adjust out the solids

(4) Less than half of the time the spray dryer will be running. 365 days*0.5=182.5 days

(5) MAXIMUM GAS VENTING RATE:

- The vent rate of each PSD1 dryer is up to 9.5 kg/hr atomizing gas (nominally 6.5 kg/hr), 1.25 kg /hr bag house pulse cleaning, and 1 kg/hr system pressure control (it would modulate in compensation for low /no atomizing gas).

Thus, maximum vent rate after the condenser total max 11.75 kg/hr (rounded to 12 above).

- Note: this is the required venting rate for non-condensable N2 to maintain pressure. Solvent vapor in the vented stream is in addition to the 11.75 kg/Hr.

(6) Ignores purging system gas inventory remaining at end of batch, which is negligibly small relative to solvent in the vent

(7) Solvent Factors:

Solvent	MW	Max Cond Temp, C	Vapor Pressure @ max cond temp, (mmHg)	vol % in N2 @ 1 ATM	Solvent Factor (kg solv/ kg N2 vented)
Ethanol	46.10	5	17	2.24	0.038
Methanol	32.00	5	40	5.26	0.063
Acetone	58.10	5	89	11.71	0.275
IPA	60.10	5	11	1.45	0.032
Ethyl Acetate	88.10	5	33	4.34	0.143
Methylene Chloride	84.90	-10	90	11.84	0.407
THF	72.10	5	60	7.89	0.221

- Condenser temperatures indicated are the maximum required by the process to meet desired process and product specifications.

- Vapor Pressure Data Ref: Table 3-8, Vapor Pressures of Organic Compounds, up to 1 ATM, Table 3-8, Vapor Pressures of Organic Compounds, up to 1 Atm. Perry's Handbook, 5th ed.

(8) Calculation assumes gas is saturated at indicated maximum condenser temp.

(9) Typical solvent mix assumes the listed solvent is used an average % throughout the year

R&D Spray Dryer (PSD-1)			Potential To Emit			Expected Emission		Permit Limits	
Pollutant	VOC?	HAP?	Maximum Uncontrolled Emission Rate lb/hr[2]	Maximum Controlled Emission Rate lb/hr[1],[2]	Annual Potential To Emit (PTE) (tons/yr)[1],[2]	Expected Annual Uncontrolled Emissions (tons/yr)	Expected Annual Controlled Emissions (tons/yr)[1]	Emissions (lb/hr) after carbon beds	Annual Emissions as a 12 month rolling period (TPY)
Ethanol	Yes	No	0.169	0.017	0.247	0.123	0.012	0.099	0.025
Methanol	Yes	Yes	0.587	0.059	0.857	0.428	0.043	0.168	0.086
IPA	Yes	No	0.008	0.001	0.012	0.006	0.001	0.083	0.001
Ethyl Acetate	Yes	No	0.038	0.004	0.055	0.028	0.003	0.377	0.006
Methylene Chloride	No	Yes	0.880	0.088	1.285	3.212	0.321	0.880	0.128
Tetrahydrofuran (THF)	Yes	No	0.058	0.006	0.085	0.032	0.003	0.583	0.009
Acetone	No	No	2.543	0.254	3.713	1.124	0.112	0.727	0.371
VOC			0.86	0.09	1.26	0.62	0.06	NA	0.126
HAP			1.47	0.15	2.14	3.64	0.36	NA	0.214
Notes:									
(1) The controlled emissions assume a carbon adsorption control efficiency of 90%. There are two carbon canisters operating in series, so the actual control efficiency will be greater than 90%.									
(2) Acetone, as defined by the US EPA, is neither a VOC nor a HAP, and the totals are not included in the VOC or HAP totals.									

GMP

PSD-1

Spray Dryer

Generic Process Equipment Application

If you are using this form electronically, press F1 at any time for help

General Information

1.	Facility Name: **Hercules / Ashland Research Center**
2.	Equipment ID Number: **GMP PSD-1 Spray Dryer**
3.	Provide a brief description of Equipment or Process: **Small co-current atomized nozzle spray dryer for pharmaceutical research. The spray drying system includes a feed pump to pump the feed solution to the atomizer, an inlet gas heater to heat the process gas, a drying chamber to allow for the atomized droplets to contact the hot gas and dry the droplets, a cyclone, a baghouse and a HEPA to collect the product. The solvent evaporated in the drying chamber is recovered in a condenser for reuse/disposal. The uncontolled emissions are vented through two carbon adsorber beds in series.**
4.	Manufacturer: **Niro/GEA**
5.	Model:
6.	Serial Number:

Raw Material Information

7. Raw Materials Used in Process

If there are more than four Raw Materials used, attach additional copies of this page as needed.

	Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1.	**Active pharmaceuticals and excipients**	**N/A**	**Varies**	☐ YES ☒ NO
7.2.	**Ethanol**	**64-17-5**	**1986 kg/yr average**	☐ YES ☒ NO
7.3.	**Methanol**	**67-56-1**	**4088 kg/yr average**	☐ YES ☒ NO
7.4.	**Acetone**	**67-64-1**	**4088 kg/yr average**	☐ YES ☒ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Raw Material used.

Products Produced Information

8. Products Produced

If there are more than four Products Produced, attach additional copies of this page as needed.

	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.	**R&D pharmaceuticals**	**N/A**	**Various**	☐ YES ☒ NO
8.2.				☐ YES ☐ NO

Generic Process Equipment Application

If you are using this form electronically, press F1 at any time for help

General Information	
1.	Facility Name: **Hercules / Ashland Research Center**
2.	Equipment ID Number: **GMP PSD-1 Spray Dryer – Additional Raw Material information**
3.	Provide a brief description of Equipment or Process: **Small co-current atomized nozzle spray dryer for pharmaceutical research. The spray drying system includes a feed pump to pump the feed solution to the atomizer, an inlet gas heater to heat the process gas, a drying chamber to allow for the atomized droplets to contact the hot gas and dry the droplets, a cyclone, a baghouse and a HEPA to collect the product. The solvent evaporated in the drying chamber is recovered in a condenser for reuse/disposal. The uncontrolled emissions are vented through two carbon adsorber beds in series.**
4.	Manufacturer: **Niro/GEA**
5.	Model:
6.	Serial Number:

Raw Material Information

7. Raw Materials Used in Process

If there are more than four Raw Materials used, attach additional copies of this page as needed.

Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1. Isopropanol	67-63-0	117 kg/yr average	YES X NO
7.2. Ethyl Acetate	141-78-6	117 kg/yr average	YES X NO
7.3. Methylene Chloride	75-09-2	1168 kg/yr average	YES X NO
7.4. Tetrahydrofuran	109-99-9	117 kg/yr average	YES X NO

Products Produced Information

8. Products Produced

If there are more than four Products Produced, attach additional copies of this page as needed.

Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.			☐ YES ☐ NO
8.2.			☐ YES ☐ NO

Products Produced Information

8.3.			☐ YES ☐ NO
8.4.			☐ YES ☐ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Product Produced.

Byproducts Generated Information

9. Byproducts Generated

If there are more than four Byproducts Generated, attach additional copies of this page as needed.

	Byproduct Generated	CAS Number	Generation Rate (include units)	MSDS Attached?
9.1.				☒ YES ☐ NO
9.2.				☐ YES ☐ NO
9.3.				☐ YES ☐ NO
9.4.				☐ YES ☐ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Byproduct Generated.

General Information

10. Manufacturer's Rated Capacity or Maximum Throughput of Equipment or Process: **Maximum run rate cannot exceed 4 kg/hr**

11. Describe Important Manufacturer Specifications and/or Operating Parameters for Equipment or Process: **See attached**

Attach the Manufacturer's Specification Sheet(s) for the equipment or process.

Control Device Information

12. Is an Air Pollution Control Device Used? ☒ YES ☐ NO

If an Air Pollution Control Device is used, complete the rest of Question 12. If not, proceed to Question 13.

12.1. Is Knockout Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.11 and attach it to this application.

12.2. Is a Settling Chamber Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.10 and attach it to this application.

12.3. Is an Inertial or Cyclone Collector Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.5 and attach it to this application.

12.4. Is a Fabric Collector or Baghouse Used? ☐ YES ☒ NO

Control Device Information

If YES, complete Form AQM-4.6 and attach it to this application.
12.5. Is a Venturi Scrubber Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.8 and attach it to this application.
12.6. Is an Electrostatic Precipitator Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.7 and attach it to this application.
12.7. Is Adsorption Equipment Used? ☒ YES ☐ NO
If YES, complete Form AQM-4.2 and attach it to this application.
12.8. Is a Scrubber Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.4 and attach it to this application.
12.9. Is a Thermal Oxidizer or Afterburner Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.1 and attach it to this application.
12.10. Is a Flare Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.3 and attach it to this application.
12.11. Is Any Other Control Device Used? ☐ YES ☒ NO
If YES, attach a copy of the control device Manufacturer's Specification Sheet(s).
If any other control device is used, complete the rest of Question 12. If not, proceed to Question 13.
12.12. Describe Control Device:
12.13. Pollutants Controlled: ☐ VOCs ☐ HAPs ☐ PM ☐ PM_{10} ☐ $PM_{2.5}$ ☐ NO_X ☐ SO_X ☐ Metals ☐ Other (Specify):
12.14. Control Device Manufacturer:
12.15. Control Device Model:
12.16. Control Device Serial Number:
12.17. Control Device Design Capacity:
12.18. Control Device Removal or Destruction Efficiency:

Stack Information

13. How Does the Process Equipment Vent: *(check all that apply)* ☐ Directly to the Atmosphere ☒ Through a Control Device Covered by Forms AQM-4.1 through 4.12 ☐ Through Another Control Device Described on This Form
If any of the process equipment vents directly to the atmosphere or through another control device described on this form, proceed to Question 14. If the process equipment vents through a control device, provide the stack parameters on the control device form and proceed to Question 18.
14. Number of Air Contaminant Emission Points: 1
If there are more than three Emission Points, attach additional copies of this page as needed.
For the first Emission Point

Stack Information

15.	Emission Point Name: **GMP Spray Dryer**
15.1.	Stack Height Above Grade: **10 feet**
15.2.	Stack Exit Diameter: **0.333 feet** *(Provide Stack Dimensions If Rectangular Stack)*
15.3.	Is a Stack Cap Present? ☐ YES ☒ NO
15.4.	Stack Configuration: ☐ Vertical ☐ Horizontal ☒ Downward-Venting ☐ Other (Specify): *(check all that apply)*
15.5.	Stack Exit Gas Temperature: **20 °C**
15.6.	Stack Exit Gas Flow Rate: **29.7 ACFM**
15.7.	Distance to Nearest Property Line: **362 feet**
15.8.	Describe Nearest Obstruction: **Building 8162**
15.9.	Height of Nearest Obstruction: **32 feet**
15.10.	Distance to Nearest Obstruction: **about 10 feet**
15.11.	Are Stack Sampling Ports Provided? ☐ YES ☒ NO
For the second Emission Point. If there is no second Emission Point, proceed to Question 18.	
16.	Emission Point Name:
16.1.	Stack Height Above Grade: **feet**
16.2.	Stack Exit Diameter: **feet** *(Provide Stack Dimensions If Rectangular Stack)*
16.3.	Is a Stack Cap Present? ☐ YES ☐ NO
16.4.	Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting ☐ Other (Specify): *(check all that apply)*
16.5.	Stack Exit Gas Temperature: **°F**
16.6.	Stack Exit Gas Flow Rate: **ACFM**
16.7.	Distance to Nearest Property Line: **feet**
16.8.	Describe Nearest Obstruction:
16.9.	Height of Nearest Obstruction: **feet**
16.10.	Distance to Nearest Obstruction: **feet**
16.11.	Are Stack Sampling Ports Provided? ☐ YES ☐ NO
For the third Emission Point. If there is no third Emission Point, proceed to Question 18.	
17.	Emission Point Name:
17.1.	Stack Height Above Grade: **feet**
17.2.	Stack Exit Diameter: **feet** *(Provide Stack Dimensions If Rectangular Stack)*
17.3.	Is a Stack Cap Present? ☐ YES ☐ NO
17.4.	Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting ☐ Other (Specify): *(check all that apply)*
17.5.	Stack Exit Gas Temperature: **°F**

Stack Information

17.6. Stack Exit Gas Flow Rate:	**ACFM**
17.7. Distance to Nearest Property Line:	**feet**
17.8. Describe Nearest Obstruction:	
17.9. Height of Nearest Obstruction:	**feet**
17.10. Distance to Nearest Obstruction:	**feet**
17.11. Are Stack Sampling Ports Provided?	☐ YES ☐ NO

Monitoring Information

18. Will Emissions Data be Recorded by a Continuous Emission Monitoring System?	☐ YES ☒ NO
If Yes, attach a copy of the Continuous Emission Monitoring System Manufacturer's Specification Sheets	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.1. Pollutants Monitored: ☐ VOCs ☐ HAPs ☐ PM ☐ PM_{10} ☐ $PM_{2.5}$ ☐ NO_X ☐ SO_X ☐ Metals ☐ Other (Specify):	
18.2. Describe the Continuous Emission Monitoring System:	
18.3. Manufacturer:	
18.4. Model:	
18.5. Serial Number:	
18.6. Will Multiple Emission Units Be Monitored at the Same Point?	☐ YES ☐ NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.7. Emission Units Monitored:	
18.8. Will More Than One Emission Unit be Emitting From the Combined Point At Any Time?	☐ YES ☐ NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.9. Emission Units Emitting Simultaneously:	

Voluntary Emission Limitation Request Information

19. Are You Requesting Any Voluntary Emission Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ☒ NO
If YES, complete the rest of Question 19. If NO, proceed to Question 20.	
19.1. Describe Any Requested Emission Limitations:	

Voluntary Operating Limitation Request Information

Voluntary Operating Limitation Request Information	
20. Are You Requesting Any Voluntary Operating Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ☒ NO
If YES, complete the rest of Question 20. If NO, proceed to Question 21.	
20.1. Describe Any Requested Operating Limitations:	

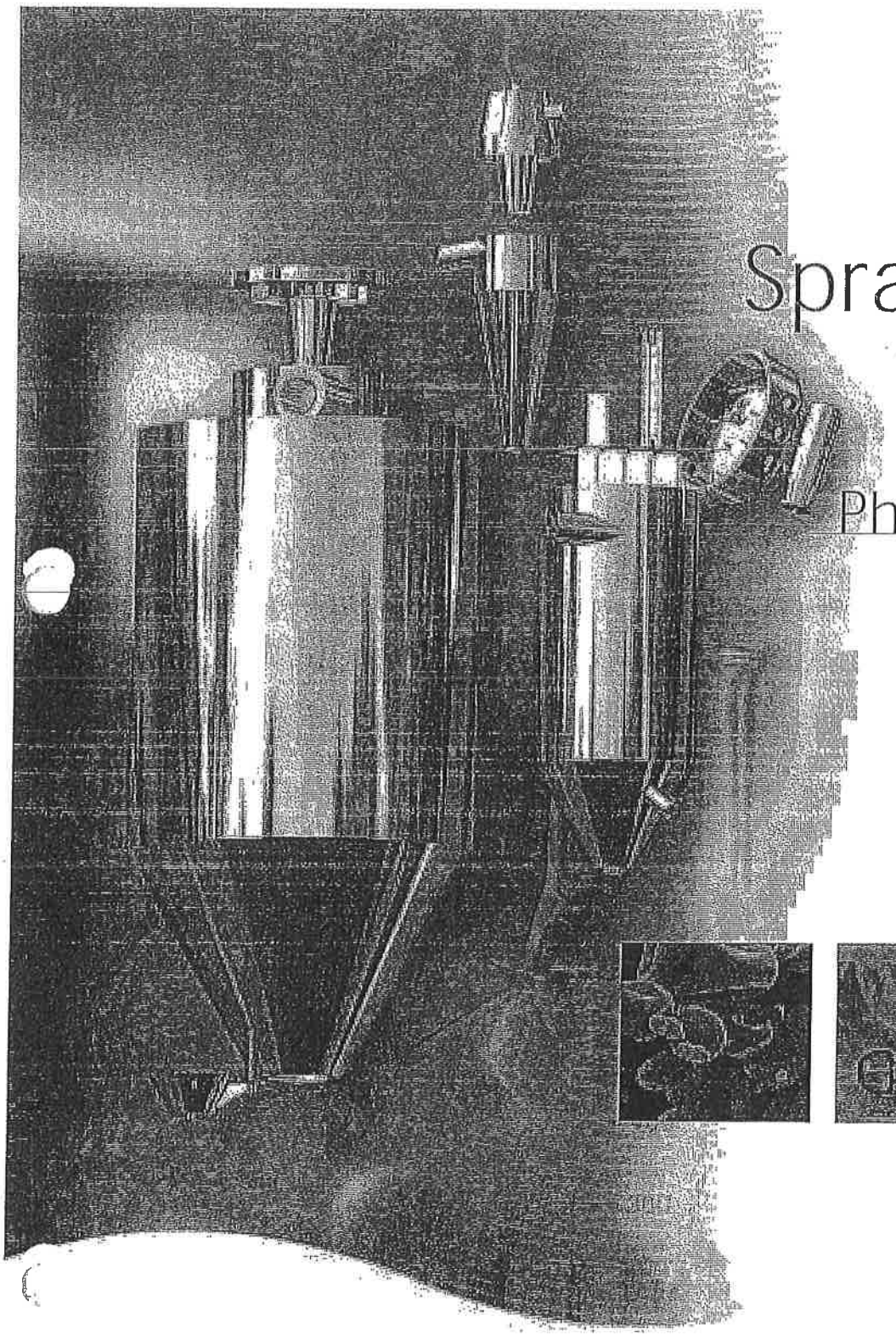
Additional Information	
21. Is There Any Additional Information Pertinent to this Application?	☐ YES ☒ NO
If YES, complete the rest of Question 21.	
21.1. Describe:	

GEA

Process Engineering
Division

Niro Pharma Systems

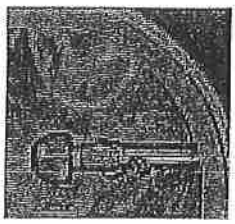
AEROMATIC BUCK COLLETTE COURTOY FIELDER NICA NIRO

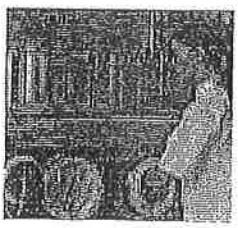


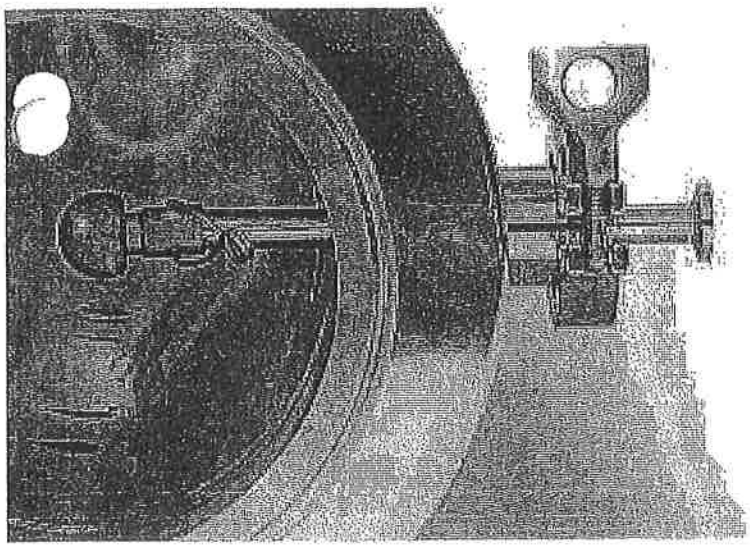
Niro Spray Dryers

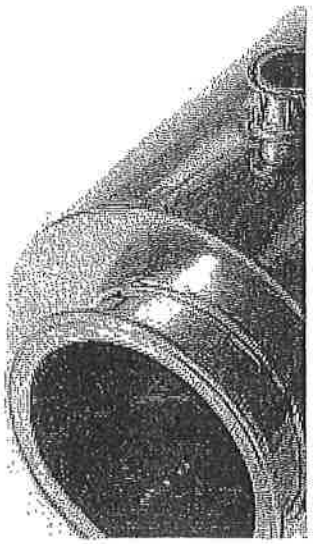
for the Pharmaceutical Industry

- Flexible
- Scalable
- Reliable
- Controllable





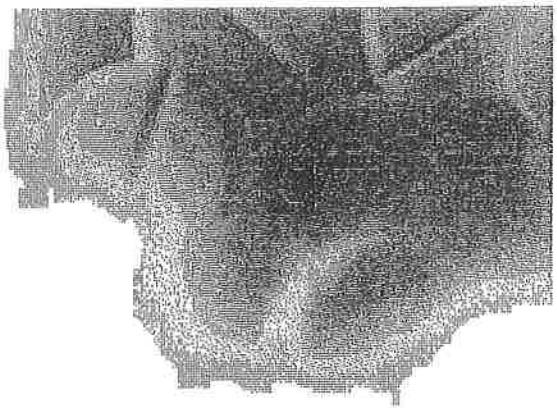




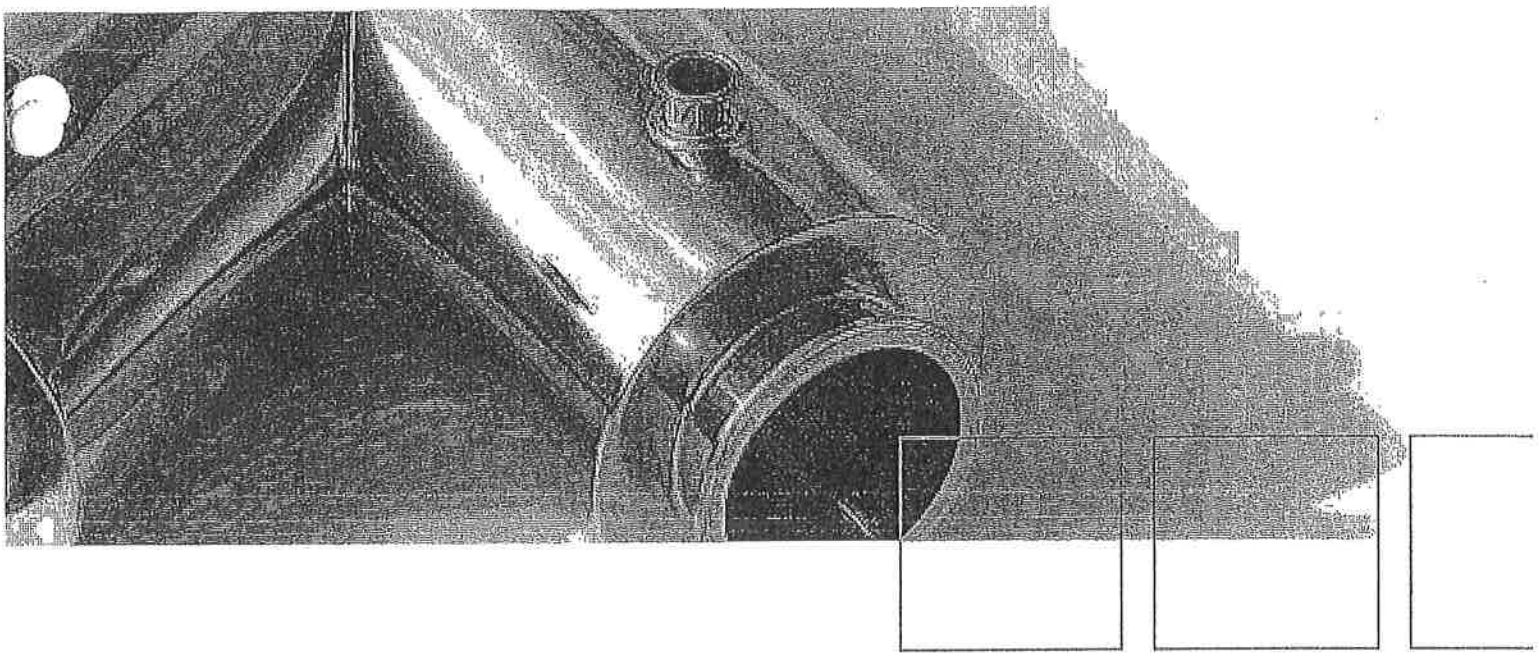
For over half a century, Niro has supplied drying plants for powders and particulates to the pharmaceutical industry. This includes a small capacity dryers designed for R & D as well as industrial size plants for continuous production of pharmaceutical compounds under cGMP conditions.

Product Know-How

– Process Expertise



Our plant and process expertise is based on experience and R & D. With plants installed around the world and literally thousands of tests performed, we have established a solid base of expertise related to the needs of the pharmaceutical manufacturing industry.



Delivering the Right Solutions

Every Niro plant begins with the customer's desire to create a product that will succeed in the market. In Niro, the customer finds a partner who will assist him to meet that goal. Our expertise includes primary as well as secondary pharmaceuticals, including technologies for processing Active Pharmaceutical Ingredients using spray drying, agglomeration, encapsulation, and spray congealing.

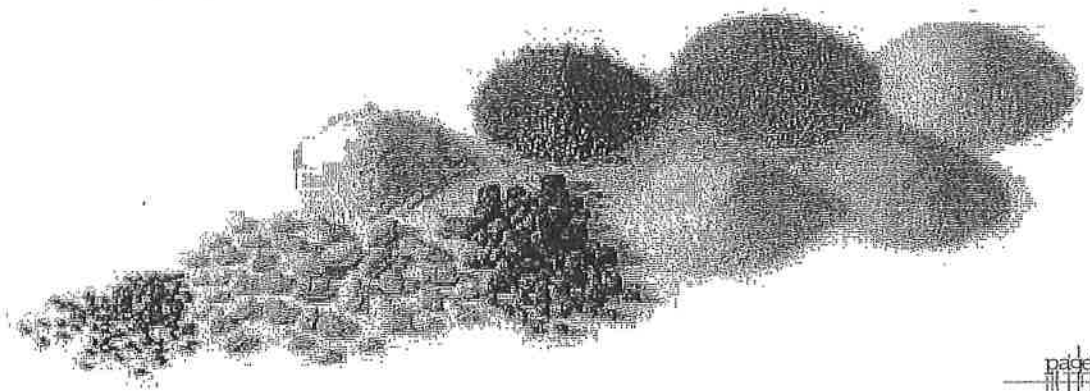
Plants Customized for Success

Every pharmaceutical plant and system from Niro is a unique union of proven technology and individual solutions. Based on standard components, we supply plants for cGMP production configured to meet the customer's specific requirements.

Among the large number of variations are: The right size to meet the customer's output requirements, the drying principle to be used, atomization configuration, and open or closed cycle operation.

A Partnership in Every Perspective

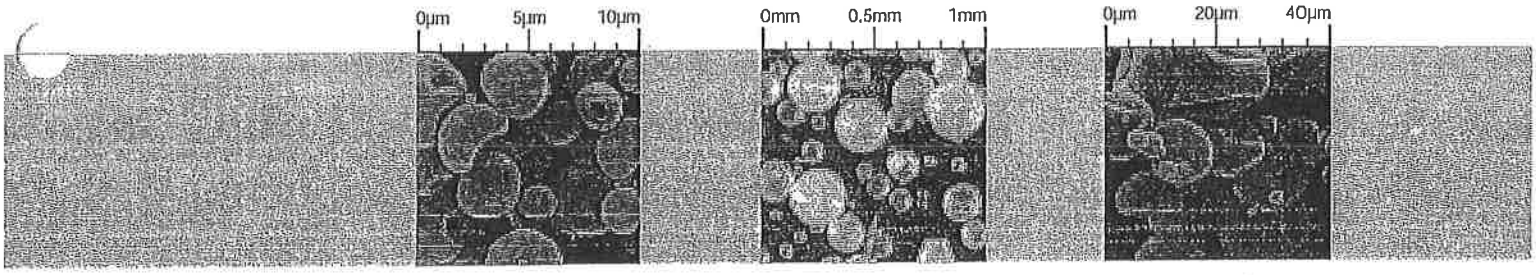
Working with Niro means entering a solid partnership every step of the way, from process testing and design to specification of the software controlling your new plant. And our comprehensive after sales program ensures that your return on investment is optimized throughout the lifetime of the plant.



Primary Pharmaceuticals

Active Pharmaceutical Ingredients (API) are typically produced by extraction or chemical syntheses. In most cases, the material is subsequently crystallized, mechanically separated, and dried. These steps can often be replaced by spray drying, which not only allows the customer to control the moisture or residual solvent content in the powder but also to create materials with a tailor-maid particle size distribution, morphology, and nature.

Secondary Pharmaceuticals



Powders for Inhalation

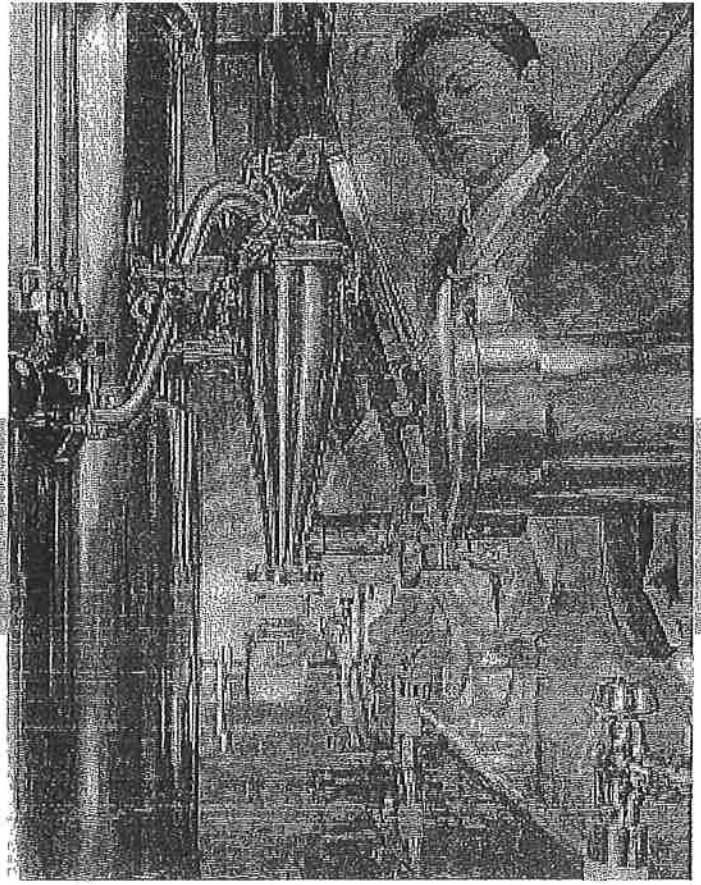
Spray drying has become the method of choice for the preparation of fine particles for inhalation. The spray dryer must be equipped with a special atomization device to produce the very fine droplets and a device for fine particle collection.

Encapsulation

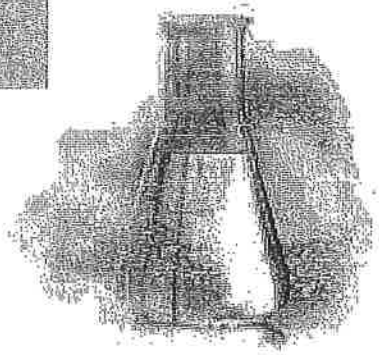
One way to achieve a constant drug level in a patient's body is to encapsulate the API in a biodegradable polymer. Controlled by diffusion, the drug is released at a constant rate over a prolonged period of time. To prepare such particles by spray drying, API and polymer are brought into solution and spray dried. Alternatively, spray congealing techniques can be used.

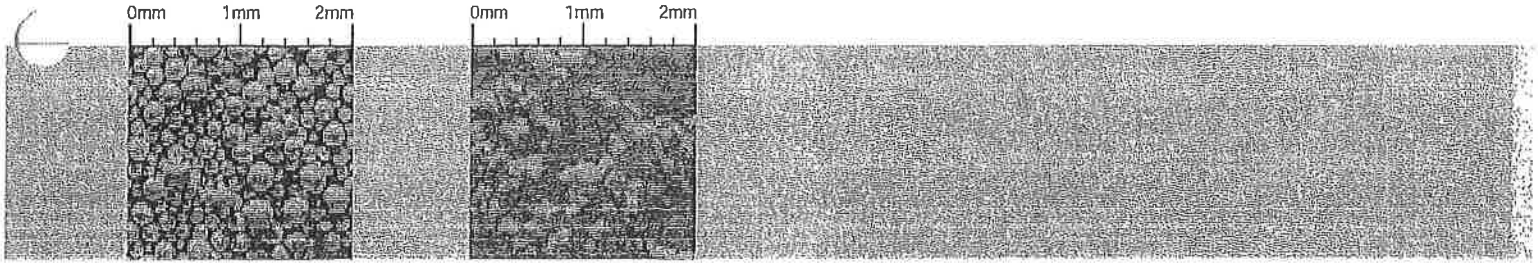
Increased Bioavailability

Some modern molecules can have a poor solubility in water or body fluids. Thus it takes an extremely long time for the API crystals to dissolve and for the drug concentration to reach the required level. If the drug product is given orally, the dissolution rate may be increased effectively by keeping the spray dried API in amorphous form using a polymer.



SD Micro™ mounted in glove box.
Spray dryer for drying very small quantities of feeds containing organic solvents





Spray Congealing

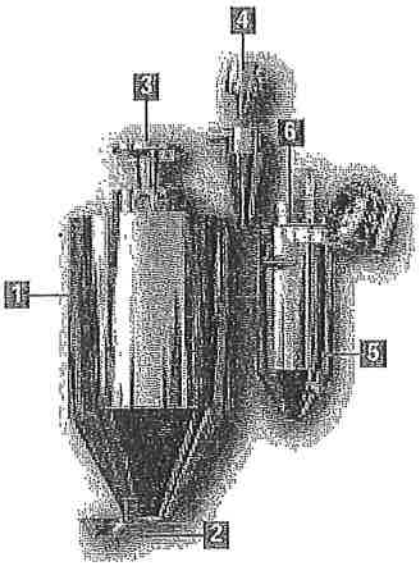
As an alternative to "classic" pharmaceutical production, it is possible to melt the active together with a polymer to enhance bioavailability. As an alternative only the polymer is molten and the active is incorporated just before atomization. The mix is then sprayed into cold process gas. This process can form a matrix in which the release can be easily controlled by the selection of the process conditions without the need for an additional coating step.

Directly Compressible

Until now, a separate granulation step has often been required in the production of solid dosage forms. The granulate is needed to avoid segregation and to assure flow properties so the dyes of a high-speed tablet press can be filled accurately. With the Fluidized Spray Dryer - FSD™ or IFD™ - concept the granulation step can be an integrated part of the continuous drying process. The FSD™ technology can also be used to achieve a low residual volatiles content in the final spray dried powder.

Sterile Excipients

Production of dry sterile dosage forms often involves large-scale mixing of the API with one or more excipients. To achieve a homogeneous mixture, the particle size distribution of the excipient(s) must match that of the API. In a one-step-operation, spray drying can turn a sterile solution of the excipient into sterile particles of the required size with no risk of introducing impurities — a well-known problem if milling is used.



Spray Drying

Standardized Customization

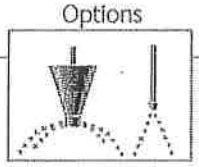
Today's increased demands for customized design, special materials of construction, special surface treatment, advanced control systems, GMP production, and process validation have resulted in continuous improvement in spray dryer design for the pharmaceutical industry.

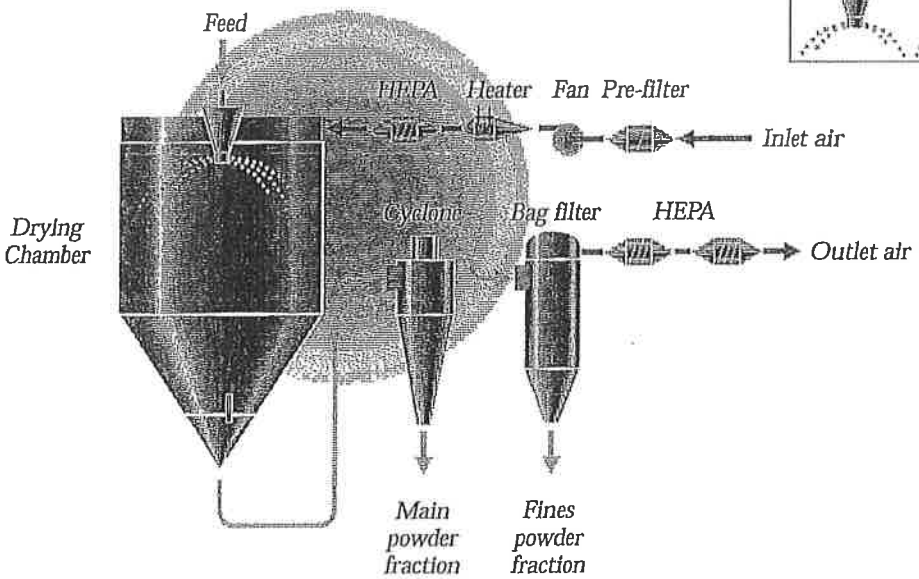
Atomization and Powder Discharge
One of the most important choices in a plant configuration is choosing the right atomization and powder discharge method. We offer a wide range of solutions as illustrated below and to the right.

1. **Spray dryer chamber**
2. **Swirl cone**
3. **Gas/air disperser**
4. **Cyclone**
5. **Bag filter**
6. **Filter bag cages**

Single Point Discharge

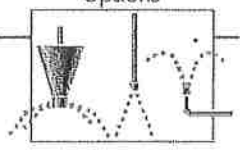
Atomizer/Nozzle Options

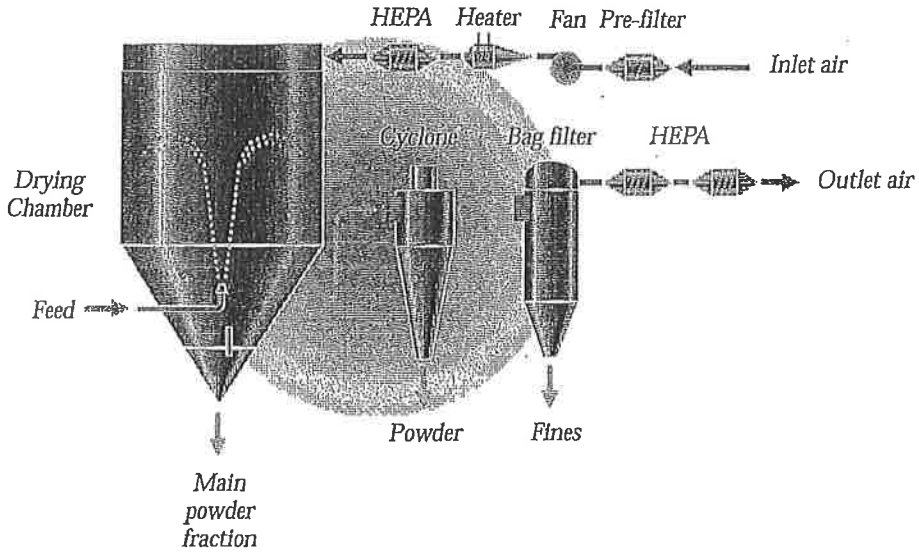




Two Point Discharge

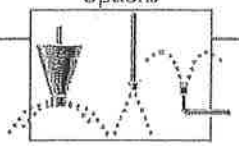
Atomizer/Nozzle Options

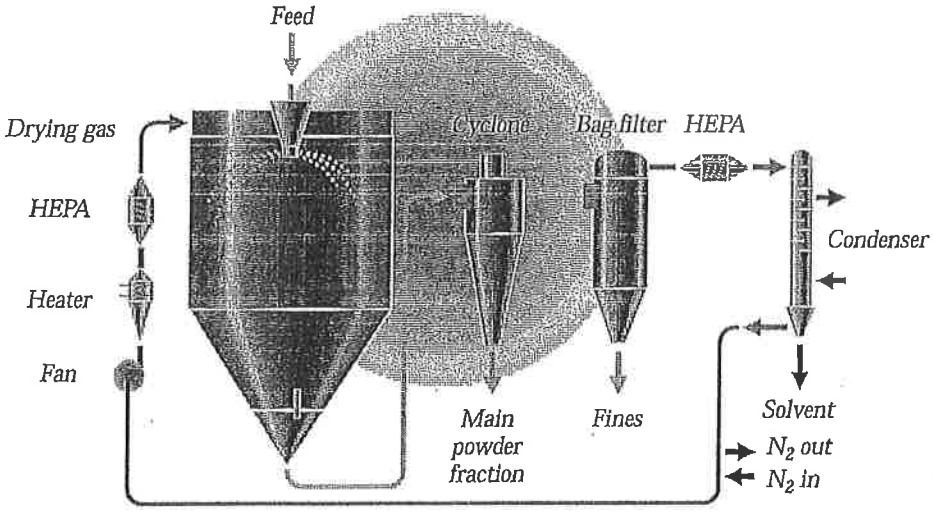




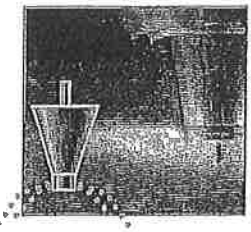
Closed Cycle Design

Atomizer/Nozzle Options

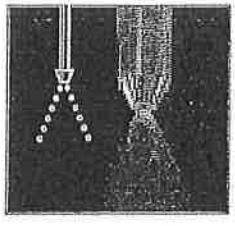




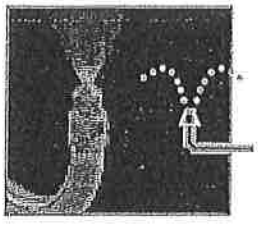
Atomizer/Nozzle Options



Rotary atomizer



Pressure or two-fluid nozzle, co-current mode



Pressure or two-fluid nozzle, fountain mode

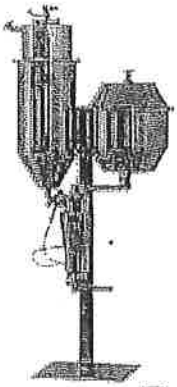
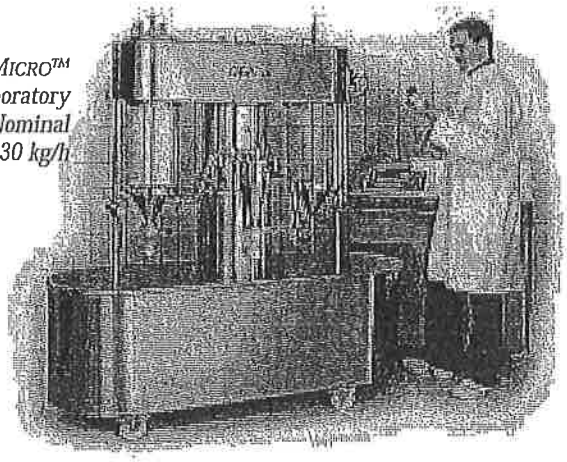


Table top aseptic spray dryer - ASEPTICSD™ Nominal drying gas rate: 30 kg/h



SDMICRO™ R&D and laboratory spray dryer. Nominal drying gas rate: 30 kg/h

PHARMASD™

Meeting Every Requirement

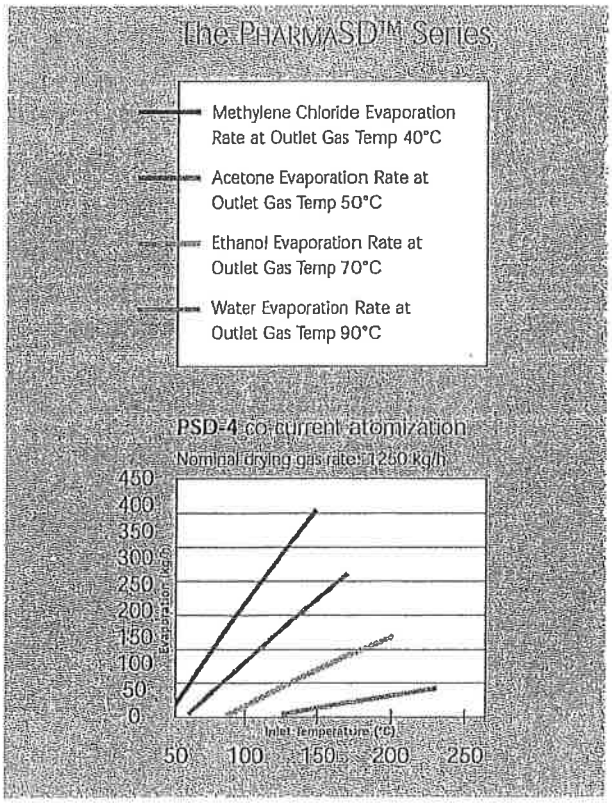
To meet the high requirements from the pharmaceutical industry, Niro has developed a series of spray dryers, the PHARMASD™ (PSD).

Tailor-Made Standard

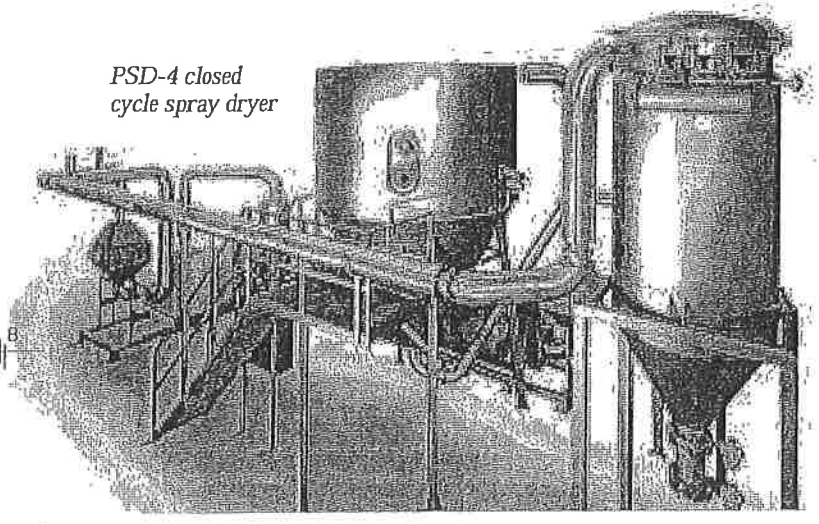
The philosophy behind the design is that a combination of standardized modules are built together in order to meet the requirement for a specific duty. Therefore, dryers of equal capacity may be completely different with respect to design, configuration and physical size.

Spray Drying Organic Solvents

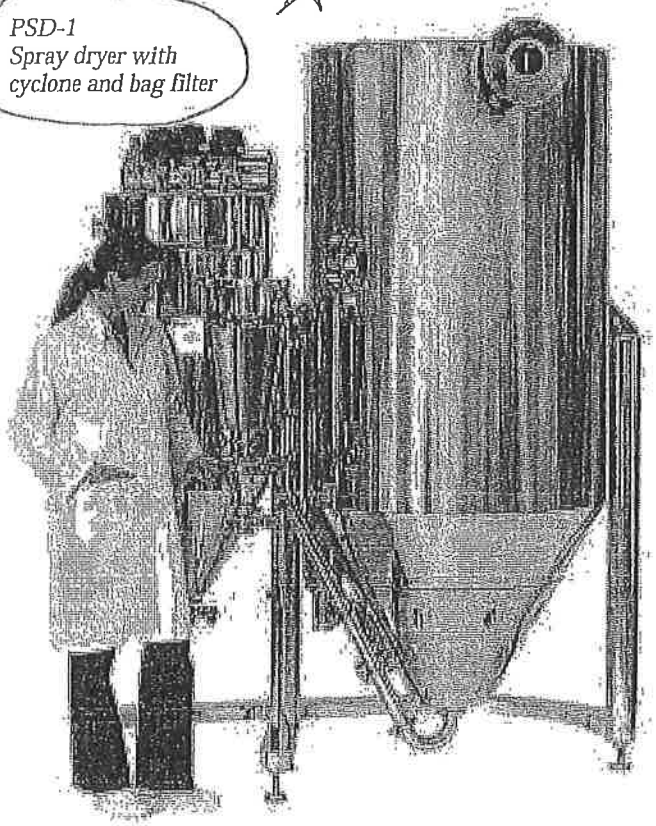
The use of solvents when preparing pharmaceutical ingredients poses a challenge in the drying process and has resulted in the use of nitrogen as a drying gas. Our spray dryers are configured for drying of compounds that are based on acetone, methylene, chloride, ethanol, and other organic solvents. The drying parameters and capacity vary greatly, depending on the solvent used, as shown in the tables below.

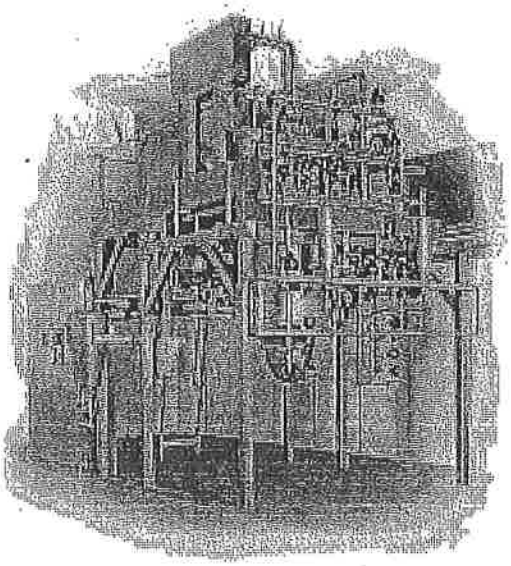


PSD-4 closed cycle spray dryer

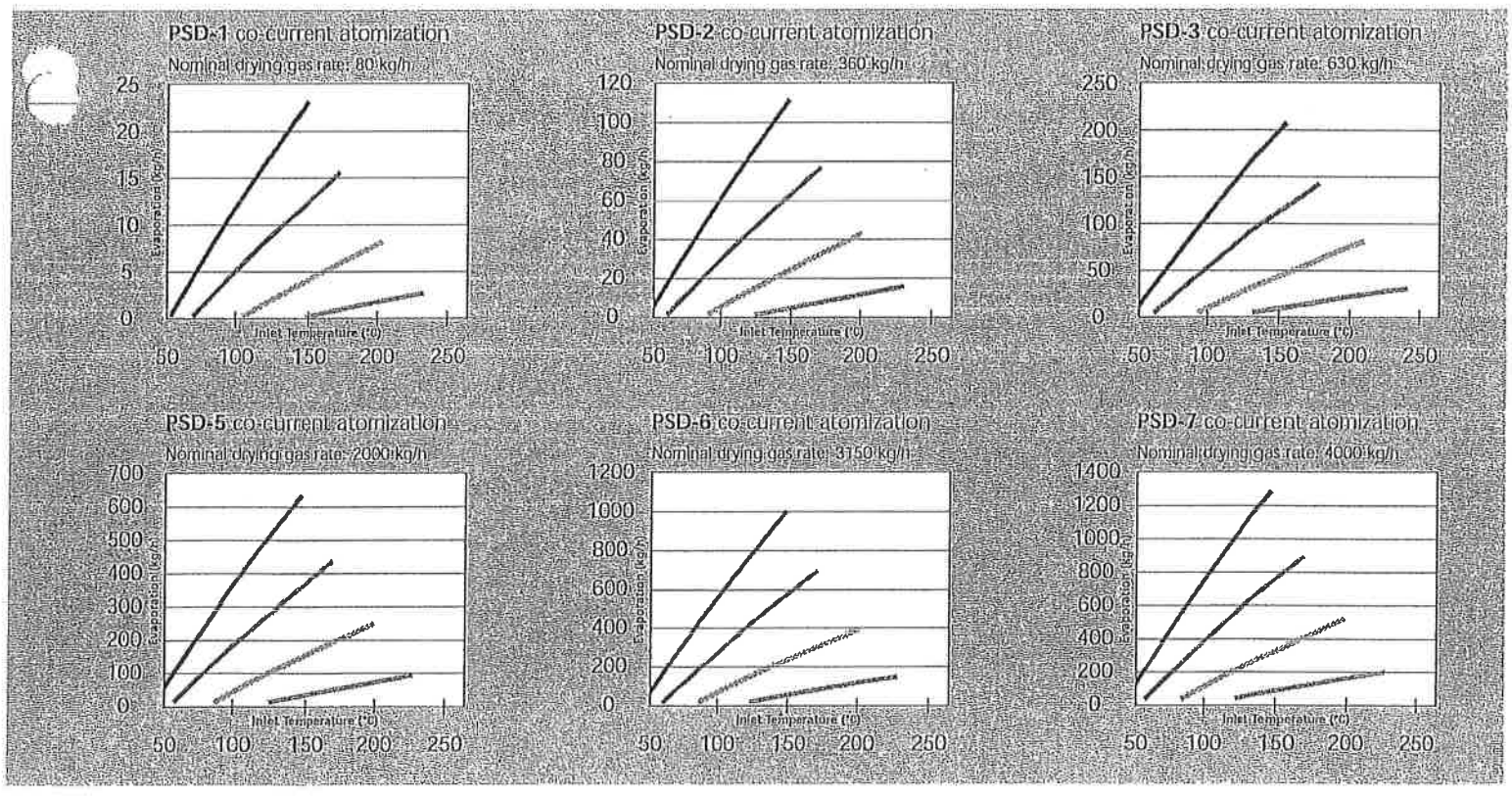


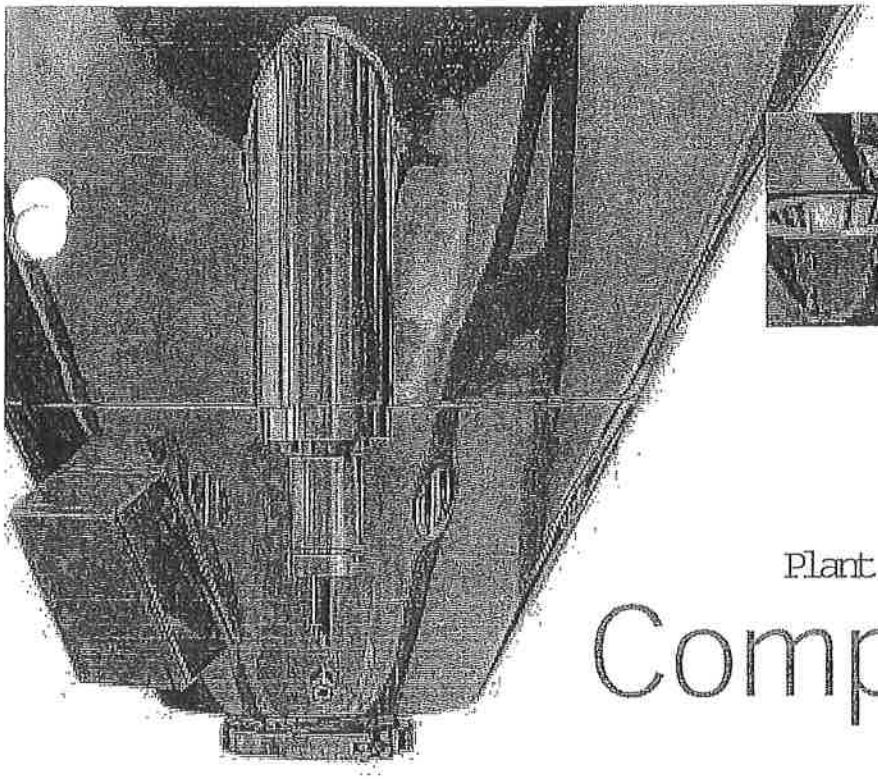
PSD-1
Spray dryer with cyclone and bag filter

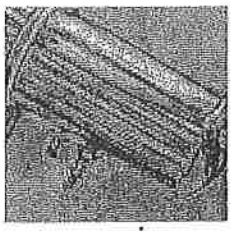


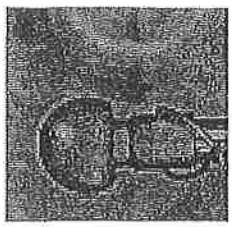


PSD-2
Spray dryer equipped with steam sterilization

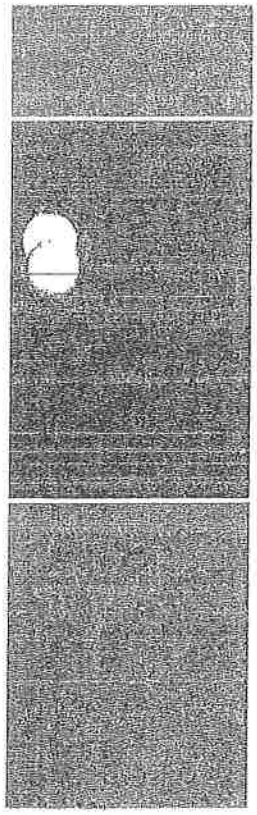








Plant Components

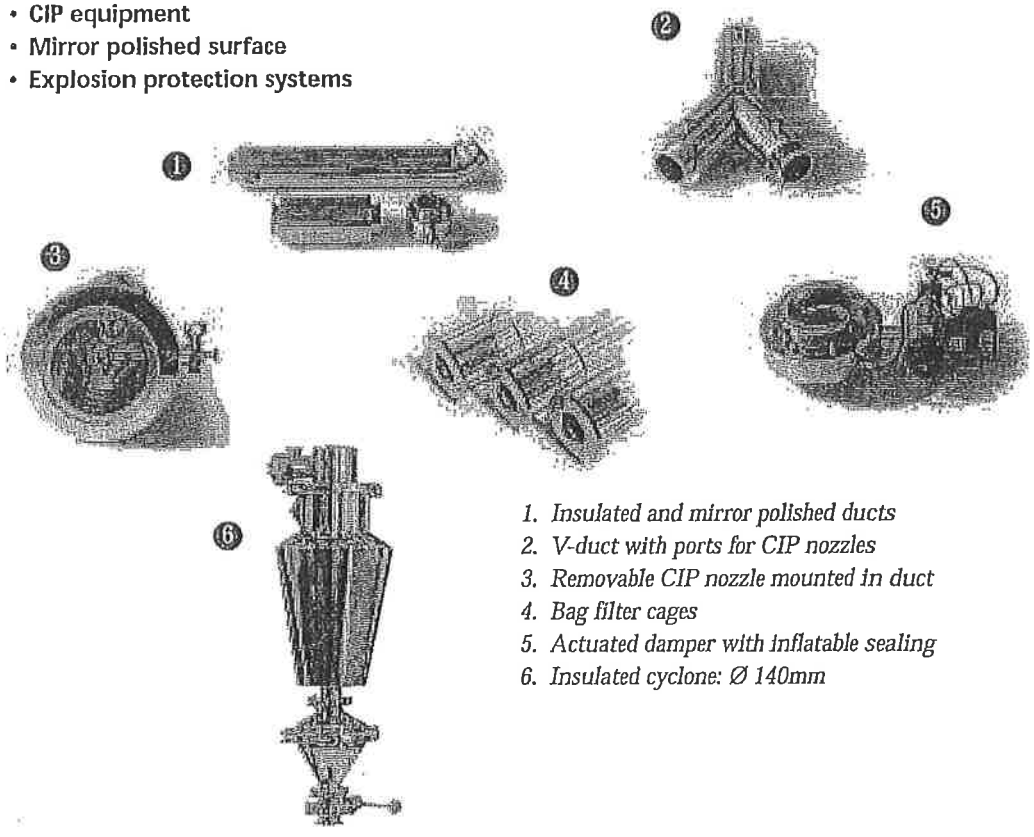


PHARMASD™ design options include:

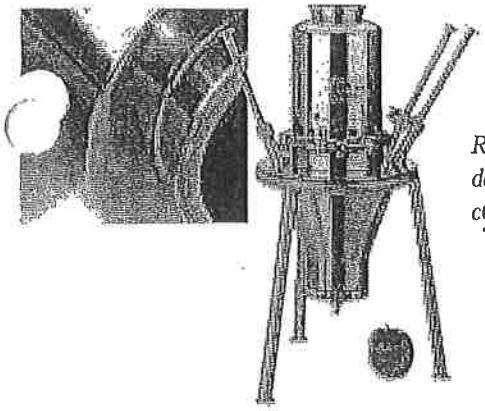
- Equipment for closed-cycle operation
- Facilities for hot gas sanitization
- Special sanitary duct connections
- Special construction materials
- HEPA filters for gas streams
- Special process gas disperser design
- Swirl cone for chamber access
- CIP equipment
- Mirror polished surface
- Explosion protection systems

Single-unit manufacturing combined with the sue of standard modules has replaced serial plant production withing the pharmaceutical industry, enabling truly customized solutions based on proven systems.

Each module, indeed each system component, must meet the strictest requirements and regulatory standards around the world.



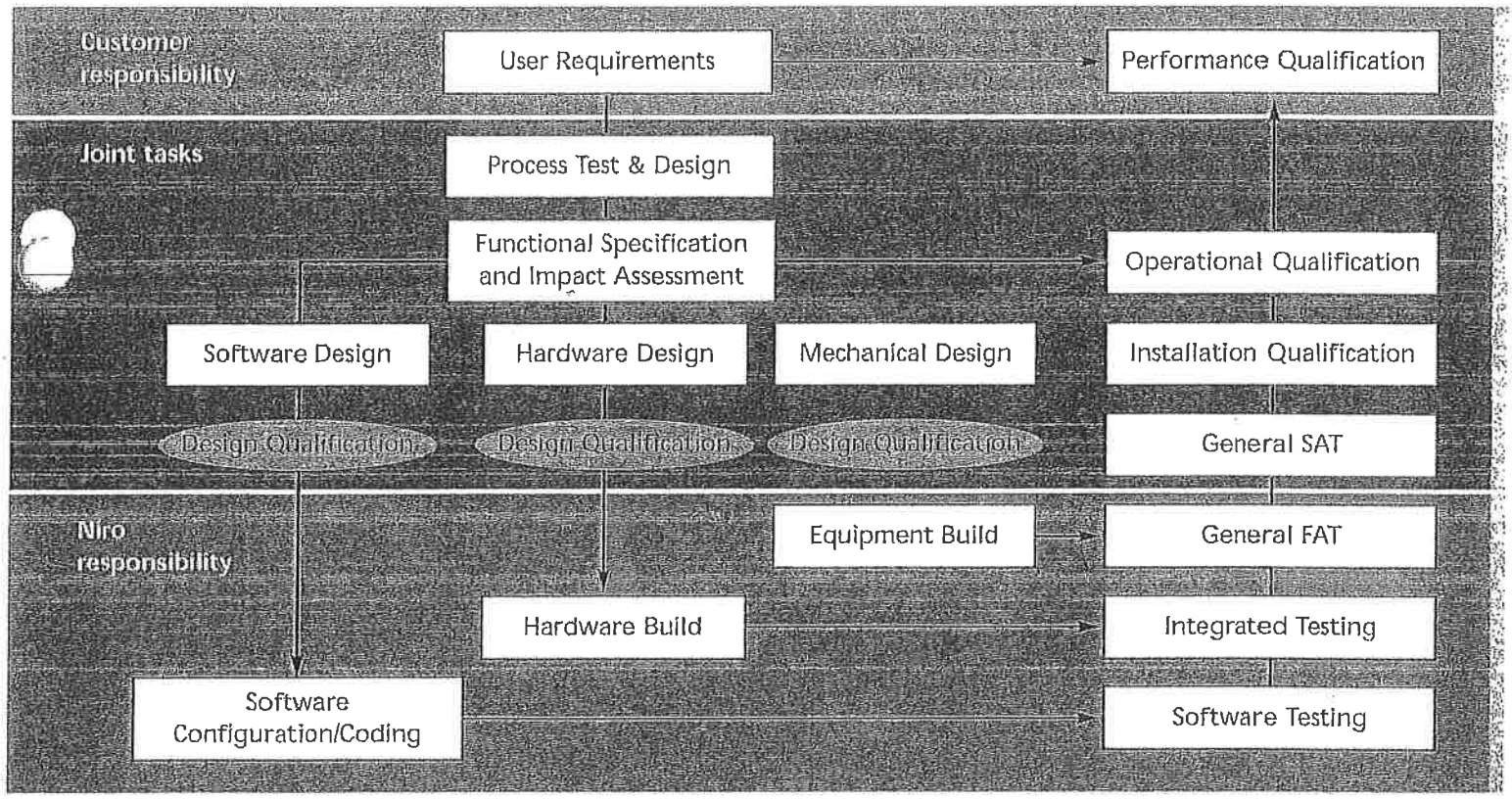
1. *Insulated and mirror polished ducts*
2. *V-duct with ports for CIP nozzles*
3. *Removable CIP nozzle mounted in duct*
4. *Bag filter cages*
5. *Actuated damper with inflatable sealing*
6. *Insulated cyclone: Ø 140mm*



Rotary atomizer F1.5 X designed to meet cGMP requirements

The Complete Partnership

Working with You...
Entering a partnership with Niro means entering a partnership that does not end until you are completely satisfied. From the moment you have specified your user requirements and until the plant has been put into service and has been qualified, our trained staff stays with you at every step of the process, working in close co-operation with your own staff creating the components and systems that will result in a finished plant.

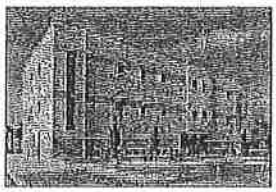


Every Step of the Way
Based on years of experience, equipment qualification will be carried out according to an agreed plan using documents prepared by Niro.

Our engineers will contribute to a successful qualification of the equipment in close co-operation with your validation staff.

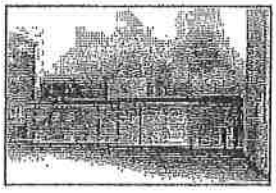
Niro Pharma Systems

AEROMATIC BUCK COLLETTE COURTOY FIELDER NICA NIRO



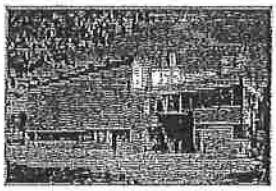
Niro Pharmaceutical Technology Centre

USA: Coating and drying technology



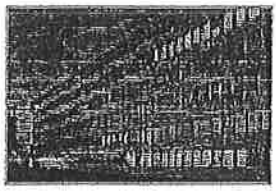
Niro Pharmaceutical Test Station

Denmark: Spray drying technology



NPS Technology Center

Switzerland: Solid dosage technology



Niro A/S

Denmark

Niro Pharma Systems is world leader in providing advanced processing solutions for solid dosage forms to the pharmaceutical industry. Based on a dedication to research and durable quality, Niro Pharma Systems offers a wide range of solutions, from individual pieces of equipment to complete integrated plants, by uniting the state-of-the-art technologies of Aeromatic, Buck, Collette, Courtoy, Fielder, Nica and Niro.

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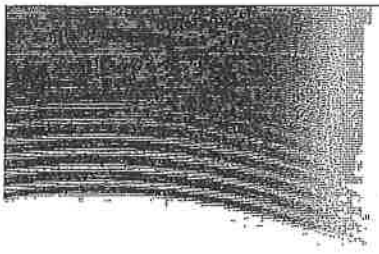


GEA Niro Pharma Systems

Process Engineering Division

A company of mg technologies group

GEA
Process Engineering
Division

Niro Inc.

SPECIFICATION
FOR
MOBILE MINOR SPRAY DRYER

1. CO-CURRENT TWO-FLUID NOZZLE ATOMIZER, externally mixing, two-fluid nozzle to be mounted in the roof of the drying chamber. The nozzle lance, body, orifice, and air cap are fabricated in stainless steel, type AISI 316. The system is supplied with a 0.5mm orifice, fittings for the air hose connection, air pressure regulator, and air flow meter.

   Compressed air must be supplied by the customer at 10 - 50 psig and a maximum of 8 scfm.

2. DRYING CHAMBER with an inside diameter of 0.8 meters and is insulated with approximately 40 mm of Rockwool covered with a stainless steel outer shell. The chamber is provided with an interior light, observation pane for inspection during operation, and one rapping stud. The rapping stud is very useful in applications where sticky materials may attempt to build up in the chamber. The interior is made of stainless steel, type AISI 316. The exterior is stainless steel, type AISI 304. The roof of the drying chamber is made of stainless steel, type AISI 316, inside, and stainless steel, type AISI 304, outside. The entire roof can be lifted, using a special pneumatic lifting device and also tilts for ease of cleaning.

3. AIR DISPERSER made of stainless steel, type AISI 304, is built into the roof and specially designed to produce the desired air flow pattern necessary for proper drying of the atomized droplets.

4. AIR DUCTS made of stainless steel, type AISI 316, are provided with quick-release threaded fasteners, to ensure easy dismantling for ease of cleaning.

5. CYCLONE made of stainless steel, type AISI 316, is designed for maximum collection efficiency and ease of cleaning. The product is collected in a one liter glass jar, threaded to the cyclone discharge.

6. EXHAUST FAN made of silumin and is driven by a direct coupled, three (3) phase squirrel cage motor, 0.5 kW. The fan is rated for an air flow of 80 kg/hr (40 cfm).

7. AIR HEATER, 10.0 kW, infinitely variable. Maximum inlet air temperature is approximately 350°C.

8. INSTRUMENT PANEL includes inlet air temperature controller, outlet air temperature indicator, and a switch for starting the fan and obtaining the base load for the electric air heater. The control panel is mounted on a mobile stand with the exhaust fan.

9. SUPPORTING STRUCTURE made of stainless steel, type AISI 304, with rubber castors for unit mobility.

10. SPARE PARTS

- one set of gaskets for cyclone and air ducts.

- one powder collecting jar.

- one filter for inlet air heater.

11. TOOLS for air duct connections.

Electrical Requirements:	230/460 Volt - 3 Ph - 60 Hz
Shipping Volume:	4.0 cubic meters (135 ft)
Gross Weight:	550 kg
Net Weight:	300 kg

Emissions Information Application

If you are using this form electronically, press F1 at any time for help

Process Information	
1.	Number of Individual Pieces of Process Equipment in Process: **1 - GMP Spray Dryer**
2.	Number of Individual Control Devices in Process: **1 - Carbon Beds**

Emissions Information for First Emission Point/Stack

3. Emission Point Name: **GMP Spray Dryer**

4. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack: **GMP Spray Dryer**

5. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 5.10 through 5.18)	CAS Number (Not required for 5.1 through 5.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
5.1.	Particulate Matter (PM)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.2.	PM_{10}		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.3.	$PM_{2.5}$		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.4.	Sulfur Oxides (SO_X)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.5.	Nitrogen Oxides (NO_X)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.6.	Carbon Monoxide (CO)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.7.	Total Volatile Organic Compounds (VOCs)		**0.86 lbs/hour**	**0.09 lbs/hour**	**1.26** tons/year	**0.127** tons/year
5.8.	Total Hazardous Air Pollutants (HAPs)		**1.47 lbs/hour**	**0.15 lbs/hour**	**2.14** tons/year	**0.215** tons/year

Emissions Information for First Emission Point/Stack

5.9. CO_2		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.10. CO_{2e}		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.11.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
5.12.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
5.13.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
5.14.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
5.15.		**lbs/hour**	**lbs/hour**	tons/year	tons/year

6. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Second Emission Point/Stack

7. Emission Point Name:

8. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

9. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 9.10 through 9.18)	CAS Number (Not required for 9.1 through 9.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
9.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year

Emissions Information for Second Emission Point/Stack

9.4.	Sulfur Oxides (SO_X)		lbs/hour	lbs/hour	tons/year	tons/year
9.5.	Nitrogen Oxides (NO_X)		lbs/hour	lbs/hour	tons/year	tons/year
9.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
9.7.	Total Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
9.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
9.9.	CO_2		lbs/hour	lbs/hour	tons/year	tons/year
9.10.	CO_{2e}		lbs/hour	lbs/hour	tons/year	tons/year
9.11.			lbs/hour	lbs/hour	tons/year	tons/year
9.12.			lbs/hour	lbs/hour	tons/year	tons/year
9.13.			lbs/hour	lbs/hour	tons/year	tons/year
9.14.			lbs/hour	lbs/hour	tons/year	tons/year
9.15.			lbs/hour	lbs/hour	tons/year	tons/year

10. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Third Emission Point/Stack

11. Emission Point Name:

12. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

13. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

Emissions Information for Third Emission Point/Stack

	Pollutant Name (Specify VOCs and HAPs Individually in 13.10 through 13.18)	CAS Number (Not required for 13.1 through 13.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
13.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.4.	Sulfur Oxides (SO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.5.	Nitrogen Oxides (NO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.6.	Carbon Monoxide (CO)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.7.	Total Volatile Organic Compounds (VOCs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.8.	Total Hazardous Air Pollutants (HAPs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.9.	CO_2		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.10.	CO_{2e}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.11.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.13.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.14.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
13.15.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

14. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Fourth Emission Point/Stack

15. Emission Point Name:

16. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

17. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 17.10 through 17.18)	CAS Number (Not required for 17.1 through 17.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
17.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.4.	Sulfur Oxides (SO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.5.	Nitrogen Oxides (NO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.6.	Carbon Monoxide (CO)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.7.	Volatile Organic Compounds (VOCs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.8.	Total Hazardous Air Pollutants (HAPs)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.9.	CO_2		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.10.	CO_{2e}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.11.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.13.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.14.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
17.15.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

Emissions Information for Fourth Emission Point/Stack

18. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

If there are more than four Emission Points/Stacks, attach additional copies of this form as needed.

Overall Process Emissions

19. Pollutant Emissions

If more than 15 pollutants are emitted from this Process, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 19.10 through 19.18)	CAS Number (Not required for 19.1 through 19.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
19.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.4.	Sulfur Oxides (SO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.5.	Nitrogen Oxides (NO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.6.	Carbon Monoxide (CO)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.7.	Total Volatile Organic Compounds (VOCs)		**0.86 lbs/hour**	**0.09 lbs/hour**	**1.26** tons/year	**0.127** tons/year
19.8.	Total Hazardous Air Pollutants (HAPs)		**1.47 lbs/hour**	**0.15 lbs/hour**	**2.14** tons/year	**0.215** tons/year
19.9.	CO_2		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.10.	CO_{2e}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

Overall Process Emissions

19.13.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.14.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.15.		**lbs/hour**	**lbs/hour**	tons/year	tons/year

20. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Minor New Source Review Information

21. Does the Process Have the Potential to Emit More Than Five Tons Per Year of Any Pollutant? ☐ YES ☒ NO

22. Is the Source New or Existing? ☒ NEW ☐ EXISTING
See Question 11 of AQM-1

If the Process has the Potential to Emit more than five tons per year of any pollutant, and is a New Source, a Control Technology Analysis pursuant to Regulation No. 1125 Section 4 must be conducted and attached to this application.

Major New Source Review Information

23. Does the Process Have the Potential to Emit More Than the Significance Level for Any Pollutant? *(Check All That Apply)*

- ☐ Greater Than 25 Tons Per Year of Particulate Matter (PM)
- ☐ Greater Than 15 Tons Per Year of PM_{10}
- ☐ Greater Than 10 Tons Per Year of $PM_{2.5}$
- ☐ Greater Than 40 Tons Per Year of Sulfur Dioxide(SO_2)
- ☐ Greater Than 25 Tons Per Year of Nitrogen Oxides (NO_X) in New Castle and Kent County
- ☐ Greater Than 100 Tons Per Year of Nitrogen Oxides (NO_X) in Sussex County
- ☐ Greater Than 100 Tons Per Year of Carbon Monoxide (CO)
- ☐ Greater Than 25 Tons Per Year of Total Volatile Organic Compounds (VOCs) in New Castle and Kent County
- ☐ Greater Than 50 Tons Per Year of Total Volatile Organic Compounds (VOCs) in Sussex County
- ☐ Greater Than 75,000 Tons Per Year of Equivalent Carbon Dioxide (CO_{2e})

If the Process has the Potential to Emit greater than any of the amounts listed above 7 DE Admin. Code 1125 Sections 2 and/or 3 apply. Contact the Department at (302) 323-4542 or (302) 739-9402 for additional information

Additional Information

24. Is There Any Additional Information Pertinent to this Application? ☐ YES ☒ NO

If YES, complete the rest of Question 24.

24.1. Describe:

Maximum Emissions Calculations, GMP Spray Dryer (PSD1) with Condenser - Updated 10/23/15, Reviewed 5/17/2016

Run rate [1]	4	kg/hr	
Run Time [2]	10.0	hr/batch	
Solvent Used [3]	40	kg/batch/day	
Operating Days/yr [4]	292	days/yr	
Solvent Spray Dried	11680	kg/yr	
Max. venting gas rate [5]	12	kg/hr NITROGEN (rounded to the next whole value)	
Operating Hours	2,920	hr/yr	
Total Gas Vented [6]	35,040	kg/yr NITROGEN vented	

Typical Solvent Mix [9]	%	kg/yr Solvent (pre condenser)	Solvent Factor [7] (kg/kg)	Calculated kg/yr exhausted [8]	Maximum kg/yr exhausted (post condenser)	Maximum lb/hr exhausted (post condenser)*	Maximum tons/year exhausted (post condenser)	Annual Emissions as a 12 month rolling period (TPY)		% Solvent	kg/yr Solvent (pre condenser)	Calculated kg/yr exhausted	Max kg/yr exhausted (post condenser)	Max lb/hr exhausted (post condenser)	Max lb/hr exhausted (post carbon beds)
										Emissions with 100% of One Solvent					
Ethanol	17.0%	1,985.6	0.04	224.4	224.4	0.169	0.247	0.025		100%	11680	1,320.0	1,320.0	0.995	0.099
Methanol	35.0%	4,088.0	0.06	778.7	778.7	0.587	0.857	0.086		100%	11680	2,224.8	2,224.8	1.676	0.168
IPA	1.0%	116.8	0.09	11.0	11.0	0.008	0.012	0.001		100%	11680	1,104.6	1,104.6	0.832	0.083
Ethy Acetate	1.0%	116.8	0.14	50.0	50.0	0.038	0.055	0.006		100%	11680	5,004.5	5,004.5	3.771	0.377
Methylene Chloride	10.0%	1,168.0	0.41	1,427.2	1,168.0	0.880	1.285	0.128		100%	11680	14,271.9	11,680.0	8.800	0.880
THF	1.0%	116.8	0.22	77.3	77.3	0.058	0.085	0.009		100%	11680	7,733.8	7,733.8	5.827	0.583
Acetone	35.0%	4,088.0	0.28	3,375.3	3,375.3	2.543	3.713	0.371		100%	11680	9,643.8	9,643.8	7.266	0.727
	65%	7,592.0	-	2,568.7	2,309.5	1.740	2.540	0.126	VOCs						
						*1 kg = 2.2 lb		0.214	HAPs						

NOTES:

(1) Based on equipment design, the max run rate cannot exceed 4 kg/hr, typically it is run at 2 kg/hr to produce quality material

(2) The equipment runs in batches, one batch per day. In between batches the time for disassembly, cleaning, drying and assembly will take at least 14 hours. The max running time per batch per day is thus 24h minus 14 hours = 10 hours

(3) This is total maximum Kg = solvent + solids. To be conservative, consider it all solvent and do not adjust out the

(4) Approximately 20% of the time throughout the year between batches, the dryer is also not running because the spray dried material needs to be characterized for particle size, particle size distribution, density, solvent content and morphology. The max running days is thus calculated as follows: (365 days)*(100%-20%)=292 days

(5) MAXIMUM GAS VENTING RATE:

- The vent rate of each PSD1 dryer is up to 9.5 kg/hr atomizing gas (nominally 6.5 kg/hr), 1.25 kg /hr bag house pulse cleaning, and 1 kg/hr system pressure control (it would modulate in compensation for low /no atomizing gas).

Thus, maximum vent rate after the condenser total max 11.75 kg/hr (rounded to 12 above).

- Note: this is the required venting rate for non-condensable N2 to maintain pressure.

Solvent vapor in the vented stream is in addition to the 11.75 kg/Hr.

(6) Ignores purging system gas inventory remaining at end of batch, which is negligibly small relative to solvent in the

(7) Solvent Factors:

Solvent	MW	Max Cond Temp, C	Vapor Pressure @ max cond temp, (mmHg)	vol % in N2 @ 1 ATM	Solvent Factor (kg solv/ kg N2 vented)
Ethanol	46.10	5	17	2.24	0.038
Methanol	32.00	5	40	5.26	0.063
Acetone	58.10	5	89	11.71	0.275
IPA	60.10	5	11	1.45	0.032
Ethy Acetate	88.10	5	33	4.34	0.143
Methylene Chloride	84.90	-10	90	11.84	0.407
THF	72.10	5	60	7.89	0.221

- Condenser temperatures indicated are the maximum required by the process to meet desired process and product specifications.

- Vapor Pressure Data Ref: Table 3-8, Vapor Pressures of Organic Compounds, up to 1 ATM, Table 3-8, Vapor Pressures of Organic Compounds, up to 1 Atm Perry's Handbook, 5th ed.

(8) Calculation assumes gas is saturated at indicated maximum condenser temp.

(9) Typical solvent mix assumes the listed solvent is used an average % throughout the year

Expected Emissions Calculations, GMP Spray Dryer (PSD1) with Condenser - Updated 10/23/15, Reviewed 5/17/2016

Run rate [1]	2	kg/hr
Run Time [2]	8.0	hr/batch
Solvent Used [3]	16	kg/batch/day
Operating Days/yr [4]	182.5	days/yr
Solvent Spray Dried	2920	kg/yr
Max. venting gas rate [5]	12	kg/hr NITROGEN (rounded to the next whole value)
Operating Hours	1,460	hr/yr
Total Gas Vented [6]	17,520	kg/yr NITROGEN vented

Typical Solvent Mix [9]	%	kg/yr Solvent (pre condenser)	Solvent Factor [7] (kg/kg)	Calculated kg/yr exhausted [8]	Expected kg/yr exhausted (post condenser)	Expected lb/hr exhausted (post condenser)*	Expected tons/year exhausted (post condenser)	%	kg/yr Solvent (pre condenser)	Calculated kg/yr exhausted	Expected kg/yr exhausted (post condenser)	Expected lb/hr exhausted (post condenser)	Expected Emissions (lb/hr) after carbon beds
Ethanol	17.0%	496.4	0.04	112.2	112.2	0.169	0.123	100%	2920	660.0	660.0	0.995	0.099
Methanol	35.0%	1,022.0	0.06	389.3	389.3	0.587	0.428	100%	2920	1,112.4	1,112.4	1.676	0.168
IPA	1.0%	29.2	0.03	5.5	5.5	0.008	0.006	100%	2920	552.3	552.3	0.832	0.083
Ethyl Acetate	1.0%	29.2	0.14	25.0	25.0	0.038	0.028	100%	2920	2,502.3	2,502.3	3.771	0.377
Methylene Chloride	100.0%	2,920.0	0.41	7,135.9	2,920.0	4.400	3.212	100%	2920	7,135.9	2,920.0	4.400	0.440
THF	1.0%	29.2	0.22	38.7	29.2	0.044	0.032	100%	2920	3,866.9	2,920.0	4.400	0.440
Acetone	35.0%	1,022.0	0.28	1,687.7	1,022.0	1.540	1.124	100%	2920	4,821.9	2,920.0	4.400	0.440
	155%	**4,526.0**	-	**7,706.7**	**3,481.3**	**5.246**	**3.829**						
						*1 kg = 2.2 lb							

NOTES:

(1) Based on equipment design, the max run rate cannot exceed 4 kg/hr, typically it is run at 2 kg/hr to produce quality material.

(2) The equipment is runs in batches, one batch per day. In between batches the time for disassembly, cleaning, drying and assembly will take at least 14 hours. The actual run time is typically less than 8 hours.

(3) This is total maximum Kg = solvent + solids. To be conservative, consider it all solvent and do not adjust out the solids

(4) Less than half of the time the spray dryer will be running. 365 days*0.5=182.5 days

(5) MAXIMUM GAS VENTING RATE:

- The vent rate of each PSD1 dryer is up to 9.5 kg/hr atomizing gas (nominally 6.5 kg/hr), 1.25 kg /hr bag house pulse cleaning, and 1 kg/hr system pressure control (it would modulate in compensation for low /no atomizing gas).

Thus, maximum vent rate after the condenser total max 11.75 kg/hr (rounded to 12 above).

- Note: this is the required venting rate for non-condensable N2 to maintain pressure. Solvent vapor in the vented stream is in addition to the 11.75 kg/Hr.

(6) Ignores purging system gas inventory remaining at end of batch, which is negligibly small relative to solvent in the vent

(7) Solvent Factors:

Solvent	MW	Max Cond Temp, C	Vapor Pressure @ max cond temp, (mmHg)	vol % in N2 @ 1 ATM	Solvent Factor (kg solv/ kg N2 vented)
Ethanol	46.10	5	17	2.24	0.038
Methanol	32.00	5	40	5.26	0.063
Acetone	58.10	5	89	11.71	0.275
IPA	60.10	5	11	1.45	0.032
Ethyl Acetate	88.10	5	33	4.34	0.143
Methylene Chloride	84.90	-10	90	11.84	0.407
THF	72.10	5	60	7.89	0.221

- Condenser temperatures indicated are the maximum required by the process to meet desired process and product specifications.
- Vapor Pressure Data Ref: Table 3-8, Vapor Pressures of Organic Compounds, up to 1 ATM, Table 3-8, Vapor Pressures of Organic Compounds, up to 1 Atm. Perry's Handbook, 5th ed.

(8) Calculation assumes gas is saturated at indicated maximum condenser temp.

(9) Typical solvent mix assumes the listed solvent is used an average % throughout the year

GMP Spray Dryer (PSD-1)			Potential To Emit			Expected Emission		Permit Limits	
Pollutant	VOC?	HAP?	Maximum Uncontrolled Emission Rate lb/hr[2]	Maximum Controlled Emission Rate lb/hr[1],[2]	Annual Potential To Emit (PTE) (tons/yr)[1],[2]	Expected Annual Uncontrolled Emissions (tons/yr)	Expected Annual Controlled Emissions (tons/yr)[1]	Emissions (lb/hr) after carbon beds	Annual Emissions as a 12 month rolling period (TPY)
Ethanol	Yes	No	0.169	0.017	0.247	0.123	0.012	0.099	0.025
Methanol	Yes	Yes	0.587	0.059	0.857	0.428	0.043	0.168	0.086
IPA	Yes	No	0.008	0.001	0.012	0.006	0.001	0.083	0.001
Ethyl Acetate	Yes	No	0.038	0.004	0.055	0.028	0.003	0.377	0.006
Methylene Chloride	No	Yes	0.880	0.088	1.285	3.212	0.321	0.880	0.128
Tetrahydrofuran (THF)	Yes	No	0.058	0.006	0.085	0.032	0.003	0.583	0.009
Acetone	No	No	2.543	0.254	3.713	1.124	0.112	0.727	0.371
VOC			0.86	0.09	1.26	0.62	0.06	NA	0.126
HAP			1.47	0.15	2.14	3.64	0.36	NA	0.214
Notes:									
(1) The controlled emissions assume a carbon adsorption control efficiency of 90%. There are two carbon canisters operating in series, so the actual control efficiency will be greater than 90%.									
(2) Acetone, as defined by the US EPA, is neither a VOC nor a HAP, and the totals are not included in the VOC or HAP totals.									

SD-Micro

Spray Dryer

Generic Process Equipment Application

If you are using this form electronically, press F1 at any time for help

General Information

1.	Facility Name: **Hercules / Ashland Research Center**
2.	Equipment ID Number: **SD Micro Spray Dryer**
3.	Provide a brief description of Equipment or Process: **Bench scale spray dryer for pharmaceutical research. The uncontrolled emissions are vented through two carbon adsorber beds in series.**
4.	Manufacturer: **Niro/GEA**
5.	Model:
6.	Serial Number: **900202**

Raw Material Information

7. Raw Materials Used in Process

If there are more than four Raw Materials used, attach additional copies of this page as needed.

	Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1.	**Active pharmaceuticals and excipients**	**N/A**	**Varies**	☐ YES ☒ NO
7.2.	**Ethanol**	**64-17-5**	**745 kg/yr average**	☐ YES ☒ NO
7.3.	**Methanol**	**67-56-1**	**1533 kg/yr average**	☐ YES ☒ NO
7.4.	**Acetone**	**67-64-1**	**1533 kg/yr average**	☐ YES ☒ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Raw Material used.

Products Produced Information

8. Products Produced

If there are more than four Products Produced, attach additional copies of this page as needed.

	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.	**R&D pharmaceuticals**	**N/A**	**Various**	☐ YES ☒ NO
8.2.				☐ YES ☐ NO
8.3.				☐ YES ☐ NO
8.4.				☐ YES ☐ NO

Generic Process Equipment Application

If you are using this form electronically, press F1 at any time for help

General Information

1.	Facility Name: **Hercules / Ashland Research Center**
2.	Equipment ID Number: **SD Micro Spray Dryer**
3.	Provide a brief description of Equipment or Process: **Bench scale spray dryer for pharmaceutical research. The uncontrolled emissions are vented through two carbon adsorber beds in series.**
4.	Manufacturer: **Niro/GEA**
5.	Model:
6.	Serial Number: **900202**

Raw Material Information

7. Raw Materials Used in Process

If there are more than four Raw Materials used, attach additional copies of this page as needed.

Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1. Isopropanol	67-63-0	44 kg/yr average	YES X NO
7.2. Ethyl Acetate	141-78-6	44 kg/yr average	YES X NO
7.3. Methylene Chloride	75-09-2	438 kg/yr average	YES X NO
7.4. Tetrahydrofuran	109-99-9	44 kg/yr average	YES X NO

Products Produced Information

8. Products Produced

If there are more than four Products Produced, attach additional copies of this page as needed.

Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.			☐ YES ☐ NO
8.2.			☐ YES ☐ NO

Products Produced Information

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Product Produced.

Byproducts Generated Information

9. Byproducts Generated

If there are more than four Byproducts Generated, attach additional copies of this page as needed.

	Byproduct Generated	CAS Number	Generation Rate (include units)	MSDS Attached?
9.1.				☒ YES ☐ NO
9.2.				☐ YES ☐ NO
9.3.				☐ YES ☐ NO
9.4.				☐ YES ☐ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Byproduct Generated.

General Information

10. Manufacturer's Rated Capacity or Maximum Throughput of Equipment or Process: **Maximum run rate cannot exceed 1.5 kg/hr**

11. Describe Important Manufacturer Specifications and/or Operating Parameters for Equipment or Process: **See attached**

Attach the Manufacturer's Specification Sheet(s) for the equipment or process.

Control Device Information

12. Is an Air Pollution Control Device Used? ☒ YES ☐ NO

If an Air Pollution Control Device is used, complete the rest of Question 12. If not, proceed to Question 13.

12.1. Is Knockout Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.11 and attach it to this application.

12.2. Is a Settling Chamber Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.10 and attach it to this application.

12.3. Is an Inertial or Cyclone Collector Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.5 and attach it to this application.

12.4. Is a Fabric Collector or Baghouse Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.6 and attach it to this application.

12.5. Is a Venturi Scrubber Used? ☐ YES ☒ NO

Control Device Information

If YES, complete Form AQM-4.8 and attach it to this application.

12.6. Is an Electrostatic Precipitator Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.7 and attach it to this application.

12.7. Is Adsorption Equipment Used? ☒ YES ☐ NO

If YES, complete Form AQM-4.2 and attach it to this application.

12.8. Is a Scrubber Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.4 and attach it to this application.

12.9. Is a Thermal Oxidizer or Afterburner Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.1 and attach it to this application.

12.10. Is a Flare Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.3 and attach it to this application.

12.11. Is Any Other Control Device Used? ☐ YES ☒ NO

If YES, attach a copy of the control device Manufacturer's Specification Sheet(s).

If any other control device is used, complete the rest of Question 12. If not, proceed to Question 13.

12.12. Describe Control Device:

12.13. Pollutants Controlled: ☐ VOCs ☐ HAPs ☐ PM ☐ PM_{10} ☐ $PM_{2.5}$ ☐ NO_X ☐ SO_X ☐ Metals ☐ Other (Specify):

12.14. Control Device Manufacturer:

12.15. Control Device Model:

12.16. Control Device Serial Number:

12.17. Control Device Design Capacity:

12.18. Control Device Removal or Destruction Efficiency:

Stack Information

13. How Does the Process Equipment Vent:
(check all that apply)
☐ Directly to the Atmosphere
☒ Through a Control Device Covered by Forms AQM-4.1 through 4.12
☐ Through Another Control Device Described on This Form

If any of the process equipment vents directly to the atmosphere or through another control device described on this form, proceed to Question 14. If the process equipment vents through a control device, provide the stack parameters on the control device form and proceed to Question 18.

14. Number of Air Contaminant Emission Points: **1**

If there are more than three Emission Points, attach additional copies of this page as needed.

For the first Emission Point

15. Emission Point Name: **SD Micro Spray Dryer**

15.1. Stack Height Above Grade: **10 feet**

Stack Information
15.2. Stack Exit Diameter: **0.333 feet** *(Provide Stack Dimensions If Rectangular Stack)*
15.3. Is a Stack Cap Present? ☐ YES ☒ NO
15.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☒ Downward-Venting *(check all that apply)* ☐ Other (Specify):
15.5. Stack Exit Gas Temperature: **20 °C**
15.6. Stack Exit Gas Flow Rate: **13 ACFM**
15.7. Distance to Nearest Property Line: **362 feet**
15.8. Describe Nearest Obstruction: **Building 8162**
15.9. Height of Nearest Obstruction: **32 feet**
15.10. Distance to Nearest Obstruction: **0 feet**
15.11. Are Stack Sampling Ports Provided? ☐ YES ☒ NO
For the second Emission Point. If there is no second Emission Point, proceed to Question 18.
16. Emission Point Name:
16.1. Stack Height Above Grade: **feet**
16.2. Stack Exit Diameter: **feet** *(Provide Stack Dimensions If Rectangular Stack)*
16.3. Is a Stack Cap Present? ☐ YES ☐ NO
16.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting *(check all that apply)* ☐ Other (Specify):
16.5. Stack Exit Gas Temperature: **°F**
16.6. Stack Exit Gas Flow Rate: **ACFM**
16.7. Distance to Nearest Property Line: **feet**
16.8. Describe Nearest Obstruction:
16.9. Height of Nearest Obstruction: **feet**
16.10. Distance to Nearest Obstruction: **feet**
16.11. Are Stack Sampling Ports Provided? ☐ YES ☐ NO
For the third Emission Point. If there is no third Emission Point, proceed to Question 18.
17. Emission Point Name:
17.1. Stack Height Above Grade: **feet**
17.2. Stack Exit Diameter: **feet** *(Provide Stack Dimensions If Rectangular Stack)*
17.3. Is a Stack Cap Present? ☐ YES ☐ NO
17.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting *(check all that apply)* ☐ Other (Specify):
17.5. Stack Exit Gas Temperature: **°F**
17.6. Stack Exit Gas Flow Rate: **ACFM**
17.7. Distance to Nearest Property Line: **feet**

Stack Information	
17.8. Describe Nearest Obstruction:	
17.9. Height of Nearest Obstruction:	**feet**
17.10. Distance to Nearest Obstruction:	**feet**
17.11. Are Stack Sampling Ports Provided?	☐ YES ☐ NO

Monitoring Information	
18. Will Emissions Data be Recorded by a Continuous Emission Monitoring System?	☐ YES ☒ NO
If Yes, attach a copy of the Continuous Emission Monitoring System Manufacturer's Specification Sheets	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.1. Pollutants Monitored: ☐ VOCs ☐ HAPs ☐ PM ☐ PM_{10} ☐ $PM_{2.5}$ ☐ NO_X ☐ SO_X ☐ Metals ☐ Other (Specify):	
18.2. Describe the Continuous Emission Monitoring System:	
18.3. Manufacturer:	
18.4. Model:	
18.5. Serial Number:	
18.6. Will Multiple Emission Units Be Monitored at the Same Point?	☐ YES ☐ NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.7. Emission Units Monitored:	
18.8. Will More Than One Emission Unit be Emitting From the Combined Point At Any Time?	☐ YES ☐ NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.9. Emission Units Emitting Simultaneously:	

Voluntary Emission Limitation Request Information	
19. Are You Requesting Any Voluntary Emission Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ☒ NO
If YES, complete the rest of Question 19. If NO, proceed to Question 20.	
19.1. Describe Any Requested Emission Limitations:	

Voluntary Operating Limitation Request Information	
20. Are You Requesting Any Voluntary Operating Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ☒ NO

Voluntary Operating Limitation Request Information
If YES, complete the rest of Question 20. If NO, proceed to Question 21.
20.1. Describe Any Requested Operating Limitations:

Additional Information
21. Is There Any Additional Information Pertinent to this Application? ☐ YES ☒ NO
If YES, complete the rest of Question 21.
21.1. Describe:

SD Micro

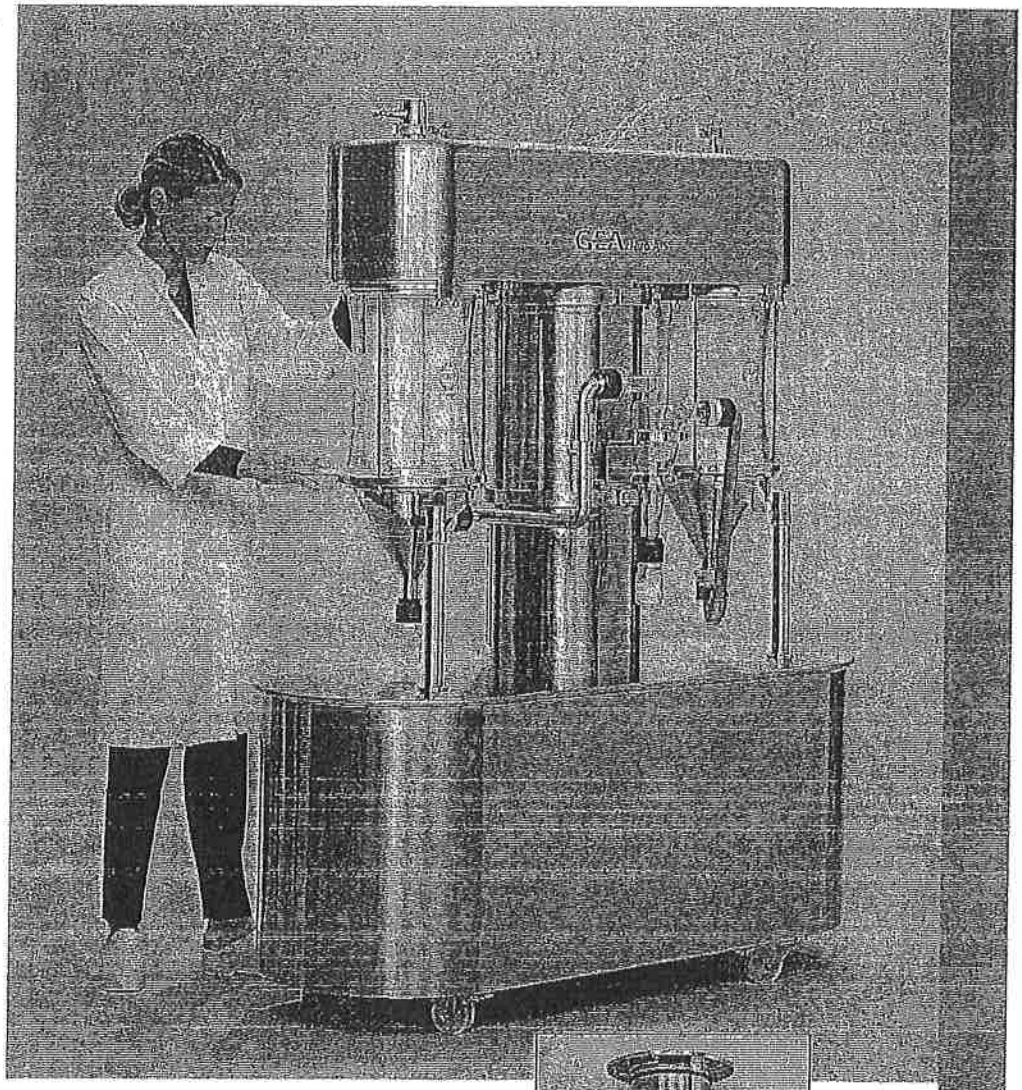
GEA

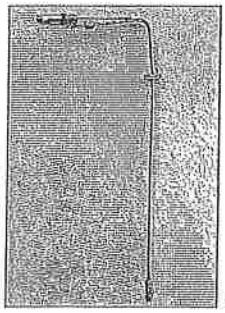
Powder Technology
Division

Niro

SDMicro™ Spray Dryer

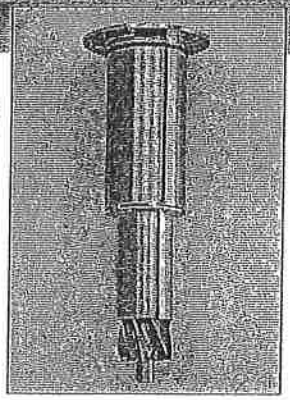
- Ideal for research and development
- Designed for spray drying of small volumes of high value pharmaceutical and chemical formulations
- Water or organic solvent based formulations can be spray dried by using compressed air or inert process gass
- Two-fluid nozzle atomization
- High efficiency cyclone and bag filter
- Easy to dismantle for cleaning and fast product switch

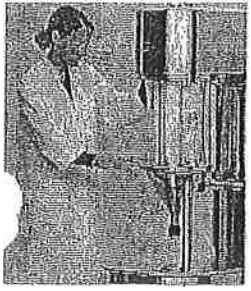




Nozzle atomizer

Process gas disperser





SDMicro™ Spray Dryer

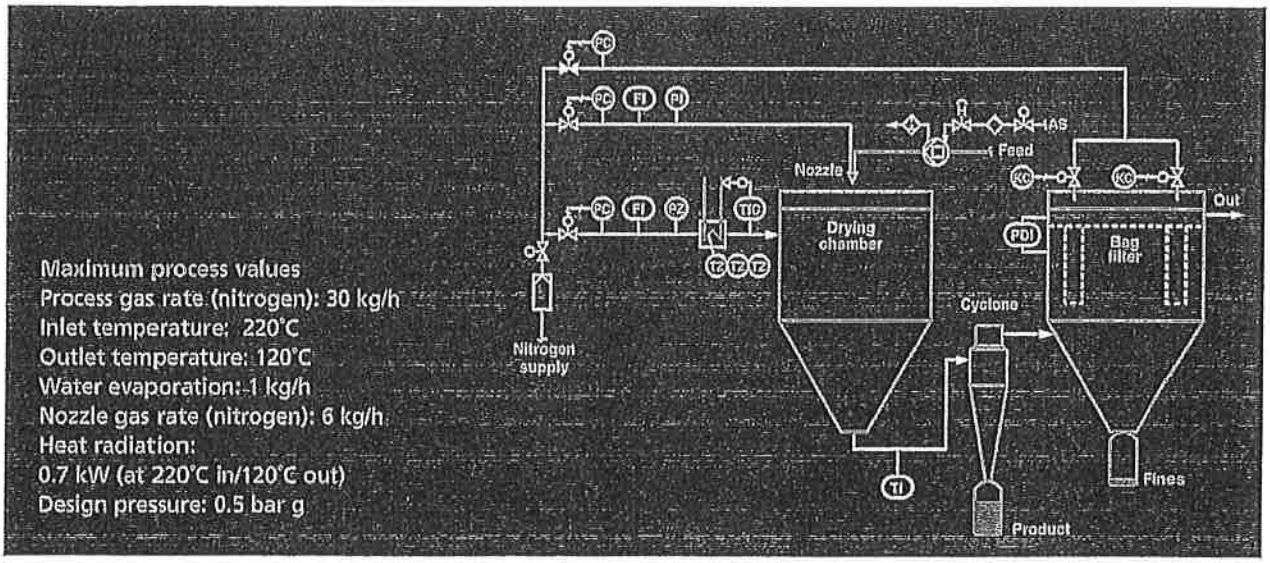
The new SDMicro™ Spray Dryer helps pharmaceutical or chemical companies to evaluate spray drying during the early stages of product development. It enables companies to identify the most appropriate isolation technique for the product to guarantee the most efficient manufacturing process.

The SDMicro™ is a fully functional spray drying plant in very small scale. Computational Fluid Dynamics have been used to design the smallest possible spray drying chamber that retained the same air flow pattern as a full scale production model. The resulting equipment can make test volumes of product at the smallest possible scale (100 - 200 ml).

The Intrinsically Safe operation makes the SDMicro™ suitable for use with Nitrogen for products dissolved in organic solvents. Compressed air is used for drying of aqueous fluids.

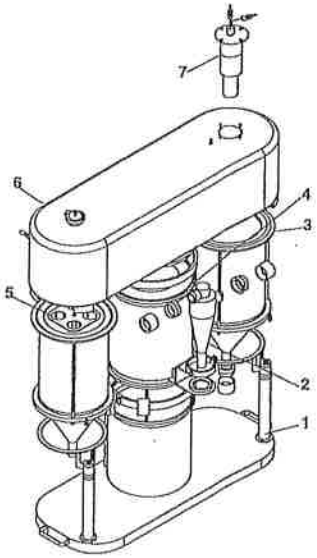
The cyclone is used for the initial powder collection, and the bag filter collects fine particles passing through the cyclone. The cyclone may be by-passed completely for collecting very fine powders in the bag filter.

The SDMicro™ is easy to dismantle for simple cleaning and fast product switching.



Configuration example

Item 1: Lower part
Item 2: Cyclone, stainless steel or glass, with powder recovery
Item 3: Drying Chamber including the two-fluid nozzle. Cylinder made of glass
Item 4: Middle section including the electrical heater, 2 kW, class EEx de IIC T1, T2, T3
Item 5: Exhaust gas bag filter. Cylinder made of glass. 4 bags of PTFE. Filter area: 0.3 m²
Continuous 'pulse jet' cleaning.
Item 6: Upper part
Item 7: Process gas disperser



Control system with animated HMI LC display
Glass type: Boro Silicate
Stainless steel: AISI 316

Dimensions

Assembled LxWxH:1200 x 600 x 1700 mm
Weight (exclusive of control panel): 200 kg
Control panel: 150 kg

GEA Niro A/S
Powder Technology Division

Niro A/S · Gladsaxevej 305 · PO Box 45 · DK-2860 Söborg · Dänemark · Tel +45 39 54 54 54 · Fax +45 39 54 58 00
E-mail: niro@niro.dk · Web-site: www.niro.dk

BNA 783/GB - 02/00 Printed in Denmark by Anton M Jensen

Emissions Information Application

If you are using this form electronically, press F1 at any time for help

Process Information

1. Number of Individual Pieces of Process Equipment in Process: **1 - SD Micro Spray Dryer**
2. Number of Individual Control Devices in Process: **1 - Carbon Beds**

Emissions Information for First Emission Point/Stack

3. Emission Point Name: **SD Micro Spray Dryer**
4. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack: **SD Micro Spray Dryer**
5. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 5.10 through 5.18)	CAS Number (Not required for 5.1 through 5.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
5.1.	Particulate Matter (PM)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.2.	PM_{10}		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.3.	$PM_{2.5}$		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.4.	Sulfur Oxides (SO_X)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.5.	Nitrogen Oxides (NO_X)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.6.	Carbon Monoxide (CO)		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.7.	Total Volatile Organic Compounds (VOCs)		**1.82 lbs/hour**	**0.18 lbs/hour**	**2.65** tons/year	**0.265** tons/year
5.8.	Total Hazardous Air Pollutants (HAPs)		**1.49 lbs/hour**	**0.15 lbs/hour**	**2.17** tons/year	**0.217** tons/year

Emissions Information for First Emission Point/Stack

5.9.	CO_2		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.10.	CO_{2e}		**0 lbs/hour**	**lbs/hour**	tons/year	tons/year
5.11.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
5.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
5.13.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
5.14.			**lbs/hour**	**lbs/hour**	tons/year	tons/year
5.15.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

6. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Second Emission Point/Stack

7. Emission Point Name:

8. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

9. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 9.10 through 9.18)	CAS Number (Not required for 9.1 through 9.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
9.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
9.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year

Emissions Information for Second Emission Point/Stack

9.4.	Sulfur Oxides (SO_X)		lbs/hour	lbs/hour	tons/year	tons/year
9.5.	Nitrogen Oxides (NO_X)		lbs/hour	lbs/hour	tons/year	tons/year
9.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
9.7.	Total Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
9.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
9.9.	CO_2		lbs/hour	lbs/hour	tons/year	tons/year
9.10.	CO_{2e}		lbs/hour	lbs/hour	tons/year	tons/year
9.11.			lbs/hour	lbs/hour	tons/year	tons/year
9.12.			lbs/hour	lbs/hour	tons/year	tons/year
9.13.			lbs/hour	lbs/hour	tons/year	tons/year
9.14.			lbs/hour	lbs/hour	tons/year	tons/year
9.15.			lbs/hour	lbs/hour	tons/year	tons/year

10. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Third Emission Point/Stack

11. Emission Point Name:

12. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

13. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

Emissions Information for Third Emission Point/Stack

	Pollutant Name (Specify VOCs and HAPs individually in 13.10 through 13.18)	CAS Number (Not required for 13.1 through 13.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
13.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
13.2.	PM_{10}		lbs/hour	lbs/hour	tons/year	tons/year
13.3.	$PM_{2.5}$		lbs/hour	lbs/hour	tons/year	tons/year
13.4.	Sulfur Oxides (SO_X)		lbs/hour	lbs/hour	tons/year	tons/year
13.5.	Nitrogen Oxides (NO_X)		lbs/hour	lbs/hour	tons/year	tons/year
13.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
13.7.	Total Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
13.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
13.9.	CO_2		lbs/hour	lbs/hour	tons/year	tons/year
13.10.	CO_{2e}		lbs/hour	lbs/hour	tons/year	tons/year
13.11.			lbs/hour	lbs/hour	tons/year	tons/year
13.12.			lbs/hour	lbs/hour	tons/year	tons/year
13.13.			lbs/hour	lbs/hour	tons/year	tons/year
13.14.			lbs/hour	lbs/hour	tons/year	tons/year
13.15.			lbs/hour	lbs/hour	tons/year	tons/year

14. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Emissions Information for Fourth Emission Point/Stack

15. Emission Point Name:

16. Equipment ID Number for all Process Equipment and Control Devices Venting Through Emission Point/Stack:

17. Pollutant Emissions

If more than 15 pollutants are emitted at this Emission Point/Stack, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 17.10 through 17.18)	CAS Number (Not required for 17.1 through 17.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
17.1.	Particulate Matter (PM)		lbs/hour	lbs/hour	tons/year	tons/year
17.2.	PM_{10}		lbs/hour	lbs/hour	tons/year	tons/year
17.3.	$PM_{2.5}$		lbs/hour	lbs/hour	tons/year	tons/year
17.4.	Sulfur Oxides (SO_X)		lbs/hour	lbs/hour	tons/year	tons/year
17.5.	Nitrogen Oxides (NO_X)		lbs/hour	lbs/hour	tons/year	tons/year
17.6.	Carbon Monoxide (CO)		lbs/hour	lbs/hour	tons/year	tons/year
17.7.	Volatile Organic Compounds (VOCs)		lbs/hour	lbs/hour	tons/year	tons/year
17.8.	Total Hazardous Air Pollutants (HAPs)		lbs/hour	lbs/hour	tons/year	tons/year
17.9.	CO_2		lbs/hour	lbs/hour	tons/year	tons/year
17.10.	CO_{2e}		lbs/hour	lbs/hour	tons/year	tons/year
17.11.			lbs/hour	lbs/hour	tons/year	tons/year
17.12.			lbs/hour	lbs/hour	tons/year	tons/year
17.13.			lbs/hour	lbs/hour	tons/year	tons/year
17.14.			lbs/hour	lbs/hour	tons/year	tons/year
17.15.			lbs/hour	lbs/hour	tons/year	tons/year

Emissions Information for Fourth Emission Point/Stack

18. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

If there are more than four Emission Points/Stacks, attach additional copies of this form as needed.

Overall Process Emissions

19. Pollutant Emissions

If more than 15 pollutants are emitted from this Process, attach additional copies of this page as needed.

	Pollutant Name (Specify VOCs and HAPs Individually in 19.10 through 19.18)	CAS Number (Not required for 19.1 through 19.10)	Maximum Uncontrolled Emission Rate at Design Capacity	Maximum Controlled Emission Rate at Design Capacity	Annual Potential to Emit (PTE)	Requested Permitted Annual Emissions
19.1.	Particulate Matter (PM)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.2.	PM_{10}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.3.	$PM_{2.5}$		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.4.	Sulfur Oxides (SO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.5.	Nitrogen Oxides (NO_X)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.6.	Carbon Monoxide (CO)		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.7.	Total Volatile Organic Compounds (VOCs)		**1.82 lbs/hour**	**0.18 lbs/hour**	**2.65** tons/year	**.265** tons/year
19.8.	Total Hazardous Air Pollutants (HAPs)		**1.49 lbs/hour**	**0.15 lbs/hour**	**2.17** tons/year	**.217** tons/year
19.9.	CO_2		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.10.	CO_{2e}		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.12.			**lbs/hour**	**lbs/hour**	tons/year	tons/year

Overall Process Emissions

19.13.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.14.		**lbs/hour**	**lbs/hour**	tons/year	tons/year
19.15.		**lbs/hour**	**lbs/hour**	tons/year	tons/year

20. Provide Any Additional Information Necessary to Understanding the Emission Rates Provided Above:

Attach the Basis of Determination or Calculations for each Emission Rate provided above.

Minor New Source Review Information

21. Does the Process Have the Potential to Emit More Than Five Tons Per Year of Any Pollutant? ☐ YES ☒ NO

22. Is the Source New or Existing? ☒ NEW ☐ EXISTING
See Question 11 of AQM-1

If the Process has the Potential to Emit more than five tons per year of any pollutant, and is a New Source, a Control Technology Analysis pursuant to Regulation No. 1125 Section 4 must be conducted and attached to this application.

Major New Source Review Information

23. Does the Process Have the Potential to Emit More Than the Significance Level for Any Pollutant? *(Check All That Apply)*

- ☐ Greater Than 25 Tons Per Year of Particulate Matter (PM)
- ☐ Greater Than 15 Tons Per Year of PM_{10}
- ☐ Greater Than 10 Tons Per Year of $PM_{2.5}$
- ☐ Greater Than 40 Tons Per Year of Sulfur Dioxide(SO_2)
- ☐ Greater Than 25 Tons Per Year of Nitrogen Oxides (NO_X) in New Castle and Kent County
- ☐ Greater Than 100 Tons Per Year of Nitrogen Oxides (NO_X) in Sussex County
- ☐ Greater Than 100 Tons Per Year of Carbon Monoxide (CO)
- ☐ Greater Than 25 Tons Per Year of Total Volatile Organic Compounds (VOCs) in New Castle and Kent County
- ☐ Greater Than 50 Tons Per Year of Total Volatile Organic Compounds (VOCs) in Sussex County
- ☐ Greater Than 75,000 Tons Per Year of Equivalent Carbon Dioxide (CO_{2e})

If the Process has the Potential to Emit greater than any of the amounts listed above 7 DE Admin. Code 1125 Sections 2 and/or 3 apply. Contact the Department at (302) 323-4542 or (302) 739-9402 for additional information

Additional Information

24. Is There Any Additional Information Pertinent to this Application? ☐ YES ☒ NO

If YES, complete the rest of Question 24.

24.1. Describe:

Maximum Emissions Calculations, SDMicro - Updated 11/10/15, Reviewed 5/17/2016									
Run rate [1]	1.5	kg/hr							
Run Time [2]	10.0	hr/day							
Solvent Used [3]	15	kg/day							
Operating Days/yr [4]	292	days/yr							
Solvent Spray Dried	4380	kg/yr							
Operating Hours	2,920	hr/yr					One Solvent at 100%		
Solvent Mix	%	Maximum kg/yr exhausted	Maximum lb/hr exhausted	Maximum tons/year exhausted	Maximum lb/hr After Carbon Beds	%	Maximum kg/yr exhausted	Maximum lb/hr exhausted after carbon beds	
Ethanol	17.0%	744.6	0.561	0.819	0.0561	100%	4380	0.330	
Methanol	35.0%	1533	1.155	1.686	0.1155	100%	4380	0.330	
IPA	1.0%	43.8	0.033	0.048	0.0033	100%	4380	0.330	
Ethy Acetate	1.0%	43.8	0.033	0.048	0.0033	100%	4380	0.330	
Methylene Chloride	10.0%	438	0.330	0.482	0.033	100%	4380	0.330	
THF	1.0%	43.8	0.033	0.048	0.0033	100%	4380	0.330	
Acetone	35.0%	1533	1.155	1.686	0.1155	100%	4380	0.330	
	100%	**4380**	**3.300**	**4.818**					
			*1 kg = 2.2 lb						
NOTES:									
(1) Based on equipment design, the max run rate cannot exceed 1.5 kg/hr									
(2) The equipment runs in batches, max 6 batches per day. In between batches the time for disassembly, cleaning, drying and assembly will take at least 14 hours. The max running time per batch per day is thus 24h minus 14 hours = 10 hours									
(3) This is total maximum Kg = solvent + solids. To be conservative, consider it all solvent and do not adjust out the solids weight.									
(4) Approximately 20% of the time throughout the year between batches, the dryer is also not running because the spray dried material needs to be characterized for particle size, particle size distribution, density, solvent content and morphology. The max running days is thus calculated as follows: (365 days)*(100%-20%)=292 days									

Maximum Emissions Calculations, SDMicro - Updated 11/10/15, Reviewed 5/17/2016									
Run rate [1]		1	kg/hr						
Run Time [2]		3.0	hr/day						
Solvent Used [3]		3	kg/day						
Operating Days/yr [4]		182.5	days/yr						
Solvent Spray Dried		547.5	kg/yr						
	Operating Hours	548	hr/yr				One Solvent at 100%		
	Solvent Mix	%	Maximum kg/yr exhausted	Maximum lb/hr exhausted	Maximum tons/year exhausted	Maximum tons/year After Carbon Beds	%	Maximum kg/yr exhausted	Maximum lb/hr exhausted after carbon beds
	Ethanol	17.0%	93.075	0.374	0.102	0.0102	100%	547.5	0.220
	Methanol	35.0%	191.625	0.770	0.211	0.0211	100%	547.5	0.220
	IPA	1.0%	5.475	0.022	0.006	0.0006	100%	547.5	0.220
	Ethy Acetate	1.0%	5.475	0.022	0.006	0.0006	100%	547.5	0.220
	Methylene Chloride	10.0%	54.75	0.220	0.060	0.0060	100%	547.5	0.220
	THF	1.0%	5.475	0.022	0.006	0.0006	100%	547.5	0.220
	Acetone	35.0%	191.625	0.770	0.211	0.0211	100%	547.5	0.220
		100%	**547.5**	**2.200**	**0.602**				
				*1 kg = 2.2 lb					
	NOTES:								
	(1) Based on equipment design, the max run rate cannot exceed 1 kg/hr								
	(2) The equipment runs in batches, typiclly we run 2 batches a day, less than 1.5 hours per batch								
	(3) This is total maximum Kg = solvent + solids. To be conservative, consider it all solvent and do not adjust out the solids weight.								
	(4) In a typical year, the spray drier is operated less than 50% of the days throughout the year								

SD Micro			Potential To Emit			Expected Emission		Permit Limits	
Pollutant	VOC?	HAP?	Maximum Uncontrolled Emission Rate lb/hr[2]	Maximum Controlled Emission Rate (Mixture) lb/hr[1],[2]	Annual Potential To Emit (PTE) (tons/yr)[1],[2]	Expected Annual Uncontrolled Emissions (tons/yr)	Expected Annual Controlled Emissions (tons/yr)[1]	Emissions (lb/hr) after Carbon Beds	Annual Emissions as a 12 month rolling period (TPY)
Ethanol	Yes	No	0.561	0.056	0.819	0.102	0.010	0.33	0.082
Methanol	Yes	Yes	1.155	0.116	1.686	0.211	0.021	0.33	0.169
IPA	Yes	No	0.033	0.003	0.048	0.006	0.001	0.33	0.005
Ethyl Acetate	Yes	No	0.033	0.003	0.048	0.006	0.001	0.33	0.005
Methylene Chloride	No	Yes	0.330	0.033	0.482	0.060	0.006	0.33	0.048
Tetrahydrofuran	Yes	No	0.033	0.003	0.048	0.006	0.001	0.33	0.005
Acetone	No	No	1.155	0.116	1.686	0.211	0.021	0.33	0.169
VOC			1.82	0.18	2.65	0.33	0.03	NA	0.265
HAP			1.49	0.15	2.17	0.27	0.03	NA	0.217
Notes:									
(1) The controlled emissions assume a carbon adsorption control efficiency of 90%. There are two carbon canisters operating in series, so the actual control efficiency will be greater than 90%.									
(2) Acetone, as defined by the US EPA, is neither a VOC nor a HAP, and the totals are not included in the VOC or HAP totals.									

MP-1

Fluid Bed Dryer

Generic Process Equipment Application

If you are using this form electronically, press F1 at any time for help

General Information

1.	Facility Name: **Hercules / Ashland Research Center**
2.	Equipment ID Number: **MP-1 Fluid Bed Dryer**
3.	Provide a brief description of Equipment or Process: **Small fluid bed processor for spray drying, granulating and coating for pharmaceutical research. The uncontrolled emissions are vented through two carbon adsorber beds in series.**
4.	Manufacturer: **Aeromatic**
5.	Model:
6.	Serial Number: **97900721**

Raw Material Information

7. Raw Materials Used in Process

If there are more than four Raw Materials used, attach additional copies of this page as needed.

	Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1.	**Active pharmaceuticals and excipients**	**N/A**	**Varies**	☐ YES ☒ NO
7.2.	**Ethanol**	**64-17-5**	**1917 kg/yr average**	☐ YES ☒ NO
7.3.	**Methanol**	**67-56-1**	**0 kg/yr average**	☐ YES ☒ NO
7.4.	**Acetone**	**67-64-1**	**128 kg/yr average**	☐ YES ☒ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Raw Material used.

Products Produced Information

8. Products Produced

If there are more than four Products Produced, attach additional copies of this page as needed.

	Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.	**R&D pharmaceuticals**	**N/A**	**Various**	☐ YES ☒ NO
8.2.				☐ YES ☐ NO
8.3.				☐ YES ☐ NO
8.4.				☐ YES ☐ NO

Generic Process Equipment Application

If you are using this form electronically, press F1 at any time for help

General Information

1.	Facility Name: **Hercules / Ashland Research Center**
2.	Equipment ID Number: **MP-1 Fluid Bed Dryer**
3.	Provide a brief description of Equipment or Process: **Small fluid bed processor for spray drying, granulating and coating for pharmaceutical research. The uncontrolled emissions are vented through two carbon adsorber beds in series.**
4.	Manufacturer: **Aeromatic**
5.	Model:
6.	Serial Number: **97900721**

Raw Material Information

7. Raw Materials Used in Process

If there are more than four Raw Materials used, attach additional copies of this page as needed.

Raw Material Used	CAS Number	Usage Rate (include units)	MSDS Attached?
7.1. Isopropanol	67-63-0	511 kg/yr average	YES X NO
7.2. Ethyl Acetate	141-78-6	0 kg/yr average	YES X NO
7.3. Methylene Chloride	75-09-2	0 kg/yr average	YES X NO
7.4. Tetrahydrofuran	109-99-9	0 kg/yr average	YES X NO

Products Produced Information

8. Products Produced

If there are more than four Products Produced, attach additional copies of this page as needed.

Product Produced	CAS Number	Production Rate (include units)	MSDS Attached?
8.1.			☐ YES ☐ NO
8.2.			☐ YES ☐ NO

Products Produced Information

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Product Produced.

Byproducts Generated Information

9. Byproducts Generated

If there are more than four Byproducts Generated, attach additional copies of this page as needed.

	Byproduct Generated	CAS Number	Generation Rate (include units)	MSDS Attached?
9.1.				☒ YES ☐ NO
9.2.				☐ YES ☐ NO
9.3.				☐ YES ☐ NO
9.4.				☐ YES ☐ NO

Attach a copy of all calculations made to support the data in the table above.
Attach a Material Safety Data Sheet (MSDS) for each Byproduct Generated.

General Information

10. Manufacturer's Rated Capacity or Maximum Throughput of Equipment or Process: **Maximum run rate cannot exceed 1 kg/hr**

11. Describe Important Manufacturer Specifications and/or Operating Parameters for Equipment or Process: **See attached**

Attach the Manufacturer's Specification Sheet(s) for the equipment or process.

Control Device Information

12. Is an Air Pollution Control Device Used? ☒ YES ☐ NO

If an Air Pollution Control Device is used, complete the rest of Question 12. If not, proceed to Question 13.

12.1. Is Knockout Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.11 and attach it to this application.

12.2. Is a Settling Chamber Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.10 and attach it to this application.

12.3. Is an Inertial or Cyclone Collector Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.5 and attach it to this application.

12.4. Is a Fabric Collector or Baghouse Used? ☐ YES ☒ NO

If YES, complete Form AQM-4.6 and attach it to this application.

12.5. Is a Venturi Scrubber Used? ☐ YES ☒ NO

Control Device Information

If YES, complete Form AQM-4.8 and attach it to this application.
12.6. Is an Electrostatic Precipitator Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.7 and attach it to this application.
12.7. Is Adsorption Equipment Used? ☒ YES ☐ NO
If YES, complete Form AQM-4.2 and attach it to this application.
12.8. Is a Scrubber Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.4 and attach it to this application.
12.9. Is a Thermal Oxidizer or Afterburner Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.1 and attach it to this application.
12.10. Is a Flare Used? ☐ YES ☒ NO
If YES, complete Form AQM-4.3 and attach it to this application.
12.11. Is Any Other Control Device Used? ☐ YES ☒ NO
If YES, attach a copy of the control device Manufacturer's Specification Sheet(s).
If any other control device is used, complete the rest of Question 12. If not, proceed to Question 13.
12.12. Describe Control Device:
12.13. Pollutants Controlled: ☐ VOCs ☐ HAPs ☐ PM ☐ PM_{10} ☐ $PM_{2.5}$ ☐ NO_X ☐ SO_X ☐ Metals ☐ Other (Specify):
12.14. Control Device Manufacturer:
12.15. Control Device Model:
12.16. Control Device Serial Number:
12.17. Control Device Design Capacity:
12.18. Control Device Removal or Destruction Efficiency:

Stack Information

13. How Does the Process Equipment Vent: *(check all that apply)* ☐ Directly to the Atmosphere ☒ Through a Control Device Covered by Forms AQM-4.1 through 4.12 ☐ Through Another Control Device Described on This Form
If any of the process equipment vents directly to the atmosphere or through another control device described on this form, proceed to Question 14. If the process equipment vents through a control device, provide the stack parameters on the control device form and proceed to Question 18.
14. Number of Air Contaminant Emission Points: **1**
If there are more than three Emission Points, attach additional copies of this page as needed.
For the first Emission Point
15. Emission Point Name: **MP-1**
15.1. Stack Height Above Grade: **10 feet**

Stack Information
15.2. Stack Exit Diameter: **0.333 feet** *(Provide Stack Dimensions If Rectangular Stack)*
15.3. Is a Stack Cap Present? ☐ YES ☒ NO
15.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☒ Downward-Venting *(check all that apply)* ☐ Other (Specify):
15.5. Stack Exit Gas Temperature: **20 °C**
15.6. Stack Exit Gas Flow Rate: **29.7 ACFM**
15.7. Distance to Nearest Property Line: **362 feet**
15.8. Describe Nearest Obstruction: **Building 8162**
15.9. Height of Nearest Obstruction: **32 feet**
15.10. Distance to Nearest Obstruction: **about 10 feet**
15.11. Are Stack Sampling Ports Provided? ☐ YES ☒ NO
For the second Emission Point. If there is no second Emission Point, proceed to Question 18.
16. Emission Point Name:
16.1. Stack Height Above Grade: **feet**
16.2. Stack Exit Diameter: **feet** *(Provide Stack Dimensions If Rectangular Stack)*
16.3. Is a Stack Cap Present? ☐ YES ☐ NO
16.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting *(check all that apply)* ☐ Other (Specify):
16.5. Stack Exit Gas Temperature: **°F**
16.6. Stack Exit Gas Flow Rate: **ACFM**
16.7. Distance to Nearest Property Line: **feet**
16.8. Describe Nearest Obstruction:
16.9. Height of Nearest Obstruction: **feet**
16.10. Distance to Nearest Obstruction: **feet**
16.11. Are Stack Sampling Ports Provided? ☐ YES ☐ NO
For the third Emission Point. If there is no third Emission Point, proceed to Question 18.
17. Emission Point Name:
17.1. Stack Height Above Grade: **feet**
17.2. Stack Exit Diameter: **feet** *(Provide Stack Dimensions If Rectangular Stack)*
17.3. Is a Stack Cap Present? ☐ YES ☐ NO
17.4. Stack Configuration: ☐ Vertical ☐ Horizontal ☐ Downward-Venting *(check all that apply)* ☐ Other (Specify):
17.5. Stack Exit Gas Temperature: **°F**
17.6. Stack Exit Gas Flow Rate: **ACFM**
17.7. Distance to Nearest Property Line: **feet**

Stack Information	
17.8. Describe Nearest Obstruction:	
17.9. Height of Nearest Obstruction:	**feet**
17.10. Distance to Nearest Obstruction:	**feet**
17.11. Are Stack Sampling Ports Provided?	☐ YES ☐ NO

Monitoring Information	
18. Will Emissions Data be Recorded by a Continuous Emission Monitoring System?	☐ YES ☒ NO
If Yes, attach a copy of the Continuous Emission Monitoring System Manufacturer's Specification Sheets	
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.1. Pollutants Monitored: ☐ VOCs ☐ HAPs ☐ PM ☐ PM_{10} ☐ $PM_{2.5}$ ☐ NO_X ☐ SO_X ☐ Metals ☐ Other (Specify):	
18.2. Describe the Continuous Emission Monitoring System:	
18.3. Manufacturer:	
18.4. Model:	
18.5. Serial Number:	
18.6. Will Multiple Emission Units Be Monitored at the Same Point?	☐ YES ☐ NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.7. Emission Units Monitored:	
18.8. Will More Than One Emission Unit be Emitting From the Combined Point At Any Time?	☐ YES ☐ NO
If YES, complete the rest of Question 18. If NO, proceed to Question 19.	
18.9. Emission Units Emitting Simultaneously:	

Voluntary Emission Limitation Request Information	
19. Are You Requesting Any Voluntary Emission Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ☒ NO
If YES, complete the rest of Question 19. If NO, proceed to Question 20.	
19.1. Describe Any Requested Emission Limitations:	

Voluntary Operating Limitation Request Information	
20. Are You Requesting Any Voluntary Operating Limitations to Avoid Major Source Status, Minor New Source Review, MACT, NSPS, etc.?	☐ YES ☒ NO

Voluntary Operating Limitation Request Information
If YES, complete the rest of Question 20. If NO, proceed to Question 21.
20.1. Describe Any Requested Operating Limitations:

Additional Information
21. Is There Any Additional Information Pertinent to this Application? ☐ YES ☒ NO
If YES, complete the rest of Question 21.
21.1. Describe: